(ii) Service by the management official will not produce an anticompetitive effect with respect to the depository organization.

(b) *Presumptions.* NCUA applies the following presumptions when reviewing any application for a Regulatory Standards exemption. A proposed management official is critical to the safe and sound operations of a depository institution if:

(1) That official is approved by NCUA to serve as a director or senior executive officer of that institution pursuant to 12 CFR 701.14 or pursuant to conditions imposed on a newly chartered credit union; and

(2) The institution had operated for less than two years, was not in compliance with minimum capital requirements, or otherwise was in a ''troubled condition'' as defined in 12 CFR 701.14 at the time the service under 12 CFR 701.14 was approved.

(c) *Duration of interlock.* An interlock permitted under this section may continue until NCUA notifies the affected depository organizations otherwise. NCUA may require a credit union to terminate any interlock permitted under this section if NCUA concludes, after giving the affected persons the opportunity to respond, that the determinations under paragraph (a)(2) of this section no longer may be made. A management official may continue serving the depository organization involved in the interlock for a period of 15 months following the date of the order to terminate the interlock. NCUA may shorten this period under appropriate circumstances.

§ 711.6 Management Consignment exemption.

(a) *Criteria.* NCUA may permit an interlock that otherwise would be prohibited by the Interlocks Act and § 711.3 if NCUA, after reviewing an application submitted by the depository organization seeking an exemption, determines that the interlock would:

(1) Improve the provision of credit to low- and moderate-income areas;

(2) Increase the competitive position of a minority- or women-owned depository organization;

(3) Strengthen the management of a depository institution that has been chartered for less than two years at the time an application is filed under this part; or

(4) Strengthen the management of a depository institution that is in an unsafe or unsound condition as determined by NCUA on a case-by-case basis.

(b) *Presumptions.* NCUA applies the following presumptions when reviewing any application for a Management Consignment exemption:

(1) A proposed management official is capable of strengthening the management of a depository institution described in paragraph (a)(3) of this section if that official is approved by NCUA to serve as a director or senior executive officer of that institution pursuant to 12 CFR 701.14 or pursuant to conditions imposed on a newly chartered credit union and the institution had operated for less than two years at the time the service under 12 CFR 701.14 was approved; and

(2) A proposed management official is capable of strengthening the management of a depository institution described in paragraph (a)(4) of this section if that official is approved by NCUA to serve as a director or senior executive officer of that institution pursuant to 12 CFR 701.14 and the institution was in a ''troubled condition'' as defined under 12 CFR 701.14 at the time service under that section was approved.

(c) *Duration of interlock.* An interlock granted under this section may continue for a period of two years from the date of approval. NCUA may extend this period for one additional two-year period if the depository organization applies for an extension at least 30 days before the current exemption expires and satisfies one of the criteria specified in paragraph (a) of this section. The provisions set forth in paragraph (b) of this section also apply to applications for extensions.

§ 711.7 Change in circumstances.

(a) *Termination.* A management official shall terminate his or her service or apply for an exemption to the Interlocks Act if a change in circumstances causes the service to become prohibited under that Act. A change in circumstances may include, but is not limited to, an increase in asset size of an organization, a change in the delineation of the RMSA or community, the establishment of an office, an acquisition, a merger, a consolidation, or any reorganization of the ownership structure of a depository organization that causes a previously permissible interlock to become prohibited.

(b) *Transition period.* A management official described in paragraph (a) of this section may continue to serve the depository organization involved in the interlock for 15 months following the date of the change in circumstances. NCUA may shorten this period under appropriate circumstances.

§ 711.8 Enforcement.

Except as provided in this section, NCUA administers and enforces the Interlocks Act with respect to federally insured credit unions, and may refer any case of a prohibited interlocking relationship involving these entities to the Attorney General of the United States to enforce compliance with the Interlocks Act and this part.

[FR Doc. 96–24459 Filed 9–26–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868, 870, 872, 876, 880, 882, 884, 888, and 890

[Docket No. 95N–0084]

RIN 0910–AA31

Medical Devices; Effective Date of Requirement for Premarket Approval for Class III Preamendments Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for 41 class III medical devices. The agency has summarized its findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices.

EFFECTIVE DATE: September 27, 1996.

FOR FURTHER INFORMATION CONTACT: Melpomeni K. Jeffries, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of May 6, 1994 (59 FR 23731), FDA issued a notice of availability of a preamendments class III devices strategy document. The strategy document set forth FDA's plans for implementing the provisions of section 515(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(i)) for preamendments class III devices for which FDA had not yet required premarket approval. FDA divided the devices into three groups as referenced in the May 6, 1994, notice.

In the Federal Register of September 7, 1995 (60 FR 46718), FDA published a proposed rule to require the filing under section 515(b) of the act of a PMA or a notice of completion of a PDP for 43 class III medical devices. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposal the agency's proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and the benefits to the public from use of the device (60 FR 46718 at 46743). The September 7, 1995, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. Under section 515(b)(2)(B) of the act, FDA provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the 43 class III devices was required to be submitted by September 22, 1995. The comment period closed on January 5, 1996.

FDA received two citizens petitions requesting a change in the classification for the Automated Cell Counting Devices and the Obstetric Data Analyzer from class III to class II or I. FDA reviewed the petitions and identified the deficiencies in each one and followed up with a deficiency letter on January 16, 1996, for the Automated Cell Counting Devices, and on March 7, 1996, for the Obstetric Data Analyzer. FDA will make a decision on whether to finalize the rule to require PMA's for these devices after reviewing any additional information submitted in support of reclassification.

II. Findings With Respect to Risks and Benefits

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the proposed rule of September 7, 1995. As required by section 515(b) of the act, FDA published its findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP; and (2) the benefits to the public from the use of the device.

These findings are based on the reports and recommendations of the advisory committees (panels) for the classification of these devices along with any additional information that FDA discovered. Additional information can be found in the proposed and final rules classifying these devices as listed below:

Devices	Proposed rule	Final rule
Anesthesiology 1982 (21 CFR part 868).	November 2, 1979 (44 FR 63292).	July 16, 1982 (47 FR 31130).
Cardiovascular (21 CFR part 870).	March 9, 1979 (44 FR 13284).	February 5, 1980 (45 FR 7904).
Dental (21 CFR part 872).	December 30, 1980 (45 FR 85962).	August 12, 1987 (52 FR 30082).
Gastroenterology-Urology (21 CFR part 876).	January 23, 1981 (46 FR 7562).	November 23, 1983 (48 FR 53012).
General Hospital and Personal Use (21 CFR part 880).	August 24, 1979 (44 FR 49844).	October 21, 1980 (45 FR 69678).
Neurological (21 CFR part 882).	November 28, 1978 (43 FR 55640).	September 4, 1979 (44 FR 51726).
Obstetrical and Gynecological.	April 3, 1979 (44 FR 19894).	February 26, 1980 (45 FR 12682).
Orthopedic (21 CFR part 888).	July 2, 1982 (47 FR 29052).	September 4, 1987 (52 FR 33686).
Physical Medicine (21 CFR part 890).	August 28, 1979 (44 FR 50458).	November 23, 1983 (48 FR 53032).

III. Final Rule

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the preamble to the proposed rule and is issuing this final rule to require premarket approval of the generic type of devices for class III preamendments devices by revising parts 868, 870, 872, 876, 880, 882, 884, 888, and 890 (21 CFR parts 868, 870, 872, 876, 880, 882, 884, 888, and 890).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed with FDA within 90 days of the effective date of this regulation for any of these class III preamendment devices that were in commercial distribution before May 28, 1976, or any device that FDA has found to be substantially equivalent to such a device on or before December 26, 1996. An approved PMA or declared completed PDP is required to be in effect for any such device on or before 180 days after FDA files the application. Any other class III preamendment device subject to this rule that was not in commercial distribution before May 28, 1976, or that FDA has not found, on or before December 26, 1996, to be substantially equivalent to any class III preamendment device that was in commercial distribution before May 28, 1976, is required to have an approved PMA or declared completed PDP in effect before it may be marketed.

If a PMA or notice of completion of a PDP for any of these class III preamendment devices is not filed on or before December 26, 1996, that device will be deemed adulterated under section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)), and commercial distribution of the device will be required to cease immediately. The device may, however, be distributed for investigational use, if the requirements of the investigational device exemption (IDE) regulations (part 812 (21 CFR part 812)) are met.

Under § 812.2(d) of the IDE regulations, FDA hereby stipulates that the exemptions from the IDE requirements in § 812.2(c)(1) and (c)(2) will no longer apply to clinical investigations of these class III preamendment devices. Further, FDA concludes that investigational class III preamendment devices subject to this rule are significant risk devices as defined in § 812.3(m) and advises that as of the effective date of parts 868, 870, 872, 876, 880, 882, 884, 888, and 890 requirements of the IDE regulations regarding significant risk devices will apply to any clinical investigation of these class III preamendment devices. For any of these class III preamendment devices that is not subject to a timely filed PMA or notice of completion of a PDP or notice of completion of a PDP, an IDE must be in effect under § 812.20 on or before December 26, 1996, or distribution of the device for investigational purposes must cease. FDA advises all persons currently sponsoring a clinical investigation involving any of these class III preamendment devices to submit an IDE application to FDA no later than 60 days after the effective date of this regulation, to avoid the interruption of ongoing investigations.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) and (e)(4) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As noted above, FDA published a notice of availability of a preamendments strategy, which identified these devices as ones that FDA believed were no longer being marketed. Following publication of that notice and following publication of the proposed rule upon which this final rule is based, FDA did not receive any comments stating that there was any interest in marketing these 41 devices. Therefore, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects

21 CFR Parts 868, 870, 872, 876, 880, 882, 884, 888, and 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 868, 870, 872, 876, 880, 882, 884, 888, and 890 are amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 868.5400 is amended by revising paragraph (c) to read as follows:

§ 868.5400 Electroanesthesia apparatus.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any electroanesthesia apparatus that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an electroanesthesia apparatus that was in commercial distribution before May 28, 1976. Any other electroanesthesia apparatus shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 870—CARDIOVASCULAR DEVICES

3. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

4. Section 870.1350 is amended by revising paragraph (c) to read as follows:

§ 870.1350 Catheter balloon repair kit.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any catheter balloon repair kit that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a catheter balloon repair kit that was in commercial distribution before May 28, 1976. Any other catheter balloon repair kit shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

5. Section 870.1360 is amended by revising paragraph (c) to read as follows:

§ 870.1360 Trace microsphere.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any trace microsphere that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a trace microsphere that was in commercial distribution before May 28, 1976. Any other trace microsphere shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

6. Section 870.3850 is amended by revising paragraph (c) to read as follows:

§ 870.3850 Carotid sinus nerve stimulator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976. Any other carotid sinus nerve stimulator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

7. Section 870.5300 is amended by revising paragraph (c) to read as follows:

§ 870.5300 DC-defibrillator (including paddles).

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976. Any other DC-defibrillator (including paddles) described in paragraph (b)(1) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 872—DENTAL DEVICES

8. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

9. Section 872.3400 is amended by revising paragraph (c) to read as follows:

§ 872.3400 Karaya and sodium borate with or without acacia denture adhesive.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any karaya and sodium borate with or without acacia denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a karaya and sodium borate with or without acacia denture adhesive that was in commercial distribution before May 28, 1976. Any other karaya and sodium borate with or without acacia denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

10. Section 872.3420 is amended by revising paragraph (c) to read as follows:

§ 872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive that was in commercial distribution before May 28, 1976. Any other carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

11. Section 872.3480 is amended by revising paragraph (c) to read as follows:

§ 872.3480 Polyacrylamide polymer (modified cationic) denture adhesive.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any polyacrylamide polymer (modified cationic) denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a polyacrylamide polymer (modified cationic) denture adhesive that was in commercial distribution before May 28, 1976. Any other polyacrylamide polymer (modified cationic) denture adhesive shall have an approved PMA or a declared completed PDP in effect before being place in commercial distribution.

12. Section 872.3500 is amended by revising paragraph (c) to read as follows:

§ 872.3500 Polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive that was in commercial distribution before May 28, 1976. Any other polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

13. Section 872.3560 is amended by revising paragraph (c) to read as follows:

§ 872.3560 OTC denture reliner.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any OTC denture reliner that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an OTC denture reliner that was in commercial distribution before May 28, 1976. Any other OTC denture reliner shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

14. Section 872.3820 is amended by revising paragraph (c) to read as follows:

§ 872.3820 Root canal filling resin.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any root canal filling resin described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a root canal filling resin described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other root canal filling resin shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

15. The authority citation for 21 CFR part 876 is revised to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

16. Section 876.5220 is amended by revising paragraph (c) to read as follows:

§ 876.5220 Colonic irrigation system.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other colonic irrigation system shall have an approved PMA in effect before being placed in commercial distribution.

17. Section 876.5270 is amended by revising paragraph (c) to read as follows:

§ 876.5270 Implanted electrical urinary continence device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any implanted electrical urinary continence device that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an implanted electrical urinary continence device that was in commercial distribution before May 28, 1976. Any other implanted electrical urinary continence device shall have an approved PMA or a declared completed

PDP in effect before being placed in commercial distribution.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

18. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

19. Section 880.5760 is amended by revising paragraph (c) to read as follows:

§ 880.5760 Chemical cold pack snakebite kit.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any chemical cold pack snakebite kit that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a chemical cold pack snakebite kit that was in commercial distribution before May 28, 1976. Any other chemical cold pack snakebite kit shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 882—NEUROLOGICAL DEVICES

20. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

21. Section 882.1825 is amended by revising paragraph (c) to read as follows:

§ 882.1825 Rheoencephalograph.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any rheoencephalograph that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a rheoencephalograph that was in commercial distribution before May 28, 1976. Any other rheoencephalograph shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

22. Section 882.5150 is amended by revising paragraph (c) to read as follows:

§ 882.5150 Intravascular occluding catheter.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any intravascular occluding catheter that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an intravascular occluding catheter that was in commercial distribution before May 28, 1976. Any other intravascular occluding catheter shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

23. Section 882.5850 is amended by revising paragraph (c) to read as follows:

§ 882.5850 Implanted spinal cord stimulator for bladder evacuation.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any implanted spinal cord stimulator for bladder evacuation that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an implanted spinal cord stimulator for bladder evacuation that was in commercial distribution before May 28, 1976. Any other implanted spinal cord stimulator for bladder evacuation shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

24. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

25. Section 884.2620 is amended by revising paragraph (c) to read as follows:

§ 884.2620 Fetal electroencephalographic monitor.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any fetal electroencephalographic monitor that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a fetal electroencephalographic monitor in commercial distribution before May 28, 1976. Any other fetal electroencephalographic monitor shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

26. Section 884.2685 is amended by revising paragraph (c) to read as follows:

§ 884.2685 Fetal scalp clip electrode and applicator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any fetal scalp clip electrode and applicator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a fetal scalp clip electrode and applicator that was in commercial distribution before May 28, 1976. Any other fetal scalp clip electrode and applicator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

27. Section 884.4250 is amended by revising paragraph (c) to read as follows:

§ 884.4250 Expandable cervical dilator.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any expandable cervical dilator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an expandable cervical dilator that was in commercial distribution before May 28, 1976. Any other expandable cervical dilator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

28. Section 884.4270 is amended by revising paragraph (c) to read as follows:

§ 884.4270 Vibratory cervical dilators.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any vibratory cervical dilator that was in commercial

distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a vibratory cervical dilator that was in commercial distribution before May 28, 1976. Any other vibratory cervical dilator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

29. Section 884.5050 is amended by revising paragraph (c) to read as follows:

§ 884.5050 Metreurynter-balloon abortion system.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any metreurynter-balloon abortion system that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a metreurynter-balloon abortion system that was in commercial distribution before May 28, 1976. Any other metreurynter-balloon abortion system shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

30. Section 884.5225 is amended by revising paragraph (c) to read as follows:

§ 884.5225 Abdominal decompression chamber.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any abdominal decompression chamber that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an abdominal decompression chamber that was in commercial distribution before May 28, 1976. Any other abdominal decompression chamber shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 888—ORTHOPEDIC DEVICES

31. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c,360e, 360j, 371).

32. Section 888.3120 is amended by revising paragraph (c) to read as follows:

§ 888.3120 Ankle joint metal/polymer non-constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any ankle joint metal/polymer non-constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996, been found to be substantially equivalent to a ankle joint metal/polymer non-constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other ankle joint metal/polymer non-constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

33. Section 888.3180 is amended by revising paragraph (c) to read as follows:

§ 888.3180 Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any elbow joint humeral (hemi-elbow) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an elbow joint humeral (hemi-elbow) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other elbow joint humeral (hemi-elbow) metallic uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

34. Section 888.3200 is amended by revising paragraph (c) to read as follows:

§ 888.3200 Finger joint metal/metal constrained uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any finger joint metal/metal constrained uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a finger joint metal/metal constrained uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other finger joint metal/metal constrained uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

35. Section 888.3210 is amended by revising paragraph (c) to read as follows:

§ 888.3210 Finger joint metal/metal constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any finger joint metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a finger joint metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other finger joint metal/metal constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

36. Section 888.3220 is amended by revising paragraph (c) to read as follows:

§ 888.3220 Finger joint metal/polymer constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any finger joint metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a finger joint metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other finger joint metal/polymer constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

37. Section 888.3300 is amended by revising paragraph (c) to read as follows:

§ 888.3300 Hip joint metal constrained cemented or uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any hip joint metal constrained cemented or uncemented

prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a hip joint metal constrained cemented or uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal constrained cemented or uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

38. Section 888.3310 is amended by revising paragraph (c) to read as follows:

§ 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any hip joint metal/polymer constrained cemented or uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a hip joint metal/polymer constrained cemented or uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal/polymer constrained cemented or uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

39. Section 888.3370 is amended by revising paragraph (c) to read as follows:

§ 888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any hip joint (hemi-hip) acetabular metal cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a hip joint (hemi-hip) acetabular metal cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal (hemi-hip) acetabular metal cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

40. Section 888.3380 is amended by revising paragraph (c) to read as follows:

§ 888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

41. Section 888.3480 is amended by revising paragraph (c) to read as follows:

§ 888.3480 Knee joint femorotibial metallic constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any knee joint femorotibial metallic constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a knee joint femorotibial metallic constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint femorotibial metallic constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

42. Section 888.3540 is amended by revising paragraph (c) to read as follows:

§ 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

43. Section 888.3550 is amended by revising paragraph (c) to read as follows:

§ 888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

44. Section 888.3570 is amended by revising paragraph (c) to read as follows:

§ 888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any knee joint femoral (hemi-knee) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a knee joint femoral (hemi-knee) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint femoral (hemi-knee) metallic uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

45. Section 888.3580 is amended by revising paragraph (c) to read as follows:

§ 888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

46. Section 888.3640 is amended by revising paragraph (c) to read as follows:

§ 888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any shoulder joint metal/metal or metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a shoulder joint metal/metal or metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other shoulder joint metal/metal or metal/polymer constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

47. Section 888.3680 is amended by revising paragraph (c) to read as follows:

§ 888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis that was in commercial distribution before May 28, 1976. Any other shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

48. Section 888.3790 is amended by revising paragraph (c) to read as follows:

§ 888.3790 Wrist joint metal constrained cemented prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any wrist joint metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a wrist joint metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other wrist joint metal constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

PART 890—PHYSICAL MEDICINE DEVICES

49. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

50. Section 890.3610 is amended by revising paragraph (c) to read as follows:

§ 890.3610 Rigid pneumatic structure orthosis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any rigid pneumatic structure orthosis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a rigid pneumatic structure orthosis that was in commercial distribution before May 28, 1976. Any other rigid pneumatic structure orthosis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: September 9, 1996.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

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OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

29 CFR Part 2200

Rules of Procedure

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Final rule; extension of sunset provision.

SUMMARY: The Occupational Safety and Health Review Commission has determined that additional time is necessary to properly evaluate the efficacy of its pilot E–Z Trial program. Accordingly, the Review Commission is amending the ''sunset'' provisions of the Commissions ''E–Z Trial'' rules to extend the pilot program and additional six months.

EFFECTIVE DATE: September 27, 1996.

FOR FURTHER INFORMATION CONTACT:

Earl R. Ohman, Jr., General Counsel, (202) 606–5410.

SUPPLEMENTARY INFORMATION: On August 14, 1995 the Occupational Safety and Health Review Commission published in the Federal Register (60 FR 41805) new procedural rules for a pilot program designed to simplify and accelerate adjudication for cases that warrant a less formal, less costly process. Designated ''E–Z Trial,'' the pilot program was to run for one year, terminating on September 30, 1996. A ''sunset'' provision was inserted into the rules to effectively end the program on that date unless extended by the Commission by final rule published in the Federal Register. 29 CFR § 2200.201(b).

While the Review Commission is pleased with the progress of the pilot program, as the end of the one-year period approaches, the Review Commission has concluded that an additional six months is necessary to fully evaluate E–Z Trial and to determine what, if any, amendments are necessary. Accordingly, the Commission is revising § 2200.201(b) to extend the pilot program through March 31, 1997.