(b) If the installed MRGB has a serial number listed in paragraph (a) of this AD or has a history of shock loading, perform a magnetic drain plug inspection.

(1) If the magnetic drain plug passes inspection, the MRGB may remain in service a maximum of 100 additional hours time in service (TIS) after the effective date of this AD with a repetitive magnetic drain plug inspection at intervals not to exceed 25 hours TIS. The MRGB must then be removed from service and the conformal pinion quill shafts replaced.

(2) If the magnetic drain plug fails inspection, remove the MRGB from service prior to further flight and replace the conformal pinion quill shafts.

Note 2: Westland Helicopters, Ltd. Service Bulletin No. W30–63–75, dated November 29, 1995 (SB) pertains to the subject of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Rotorcraft Standards Staff, Rotorcraft Directorate. Operators shall submit their requests through an FAA Principal Maintenance Inspector who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff, Rotorcraft Directorate.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(f) This amendment becomes effective on January 14, 1999.

Note 4: The subject of this AD is addressed in Civil Aviation Authority (United Kingdom) AD 012–11–95.

Issued in Fort Worth, Texas, on December 21, 1998.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 98–34502 Filed 12–29–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 97N–0239]

Dental Devices; Effective Date of Requirement for Premarket Approval; Temporomandibular Joint Prostheses

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 a product development protocol (PDP) for certain devices, namely, the total temporomandibular joint (TMJ) prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis (for permanent reconstruction), and the interarticular disc prosthesis. At a later date, FDA will propose reclassifying from class III into class II the generic type of temporary mandibular condyle prosthesis intended for temporary reconstruction following surgical ablation of malignant and benign tumors. This action establishing the effective date of the premarket approval requirement for certain devices is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the FDA Modernization Act of 1997 (FDAMA).

DATES: This regulation is effective December 30, 1998.

FOR FURTHER INFORMATION CONTACT: Mary S. Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory History of the Devices

In the **Federal Register** of December 20, 1994 (59 FR 65475), FDA issued a final rule classifying the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis, and the interarticular disc prosthesis (interpositional implant) into class III. The preamble to the proposal (57 FR 43165, September 18, 1992) to classify these devices included the recommendation of the Dental Products Panel of the Medical Devices Advisory Committee (the Panel), an FDA advisory committee, which met on April 21, 1989, regarding the classification of the devices, in particular, the total TMJ prosthesis and the interarticular disc prosthesis (interpositional implant). The preamble to the reproposed rule (59 FR 6935, February 14, 1994) to classify the glenoid fossa prosthesis and the mandibular condyle prosthesis included the recommendation of the Panel that reconvened on February 11, 1993, regarding the classification of these two devices. The Panel recommended, at the April 1989 meeting, that the total TMJ prosthesis and the interarticular disc prosthesis (interpositional implant) be classified into class III, and at the February 1993 meeting, the Panel recommended that the glenoid fossa prosthesis and the mandibular condyle prosthesis also be classified into class III, and identified certain risks to health presented by the devices. The Panel believed that the devices presented a potential unreasonable risk to health and that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish performance standards which would provide reasonable assurance of the safety and effectiveness of the devices. FDA agreed with the Panel's recommendations and, in the September 18, 1992, proposal (57 FR 43165), and the February 14, 1994, reproposal (59 FR 6935), proposed that the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis and the interarticular disc prosthesis (interpositional implant) be classified into class III. The proposal and reproposal stated that FDA believed that general controls, either alone or in combination with the special controls applicable to class II devices are insufficient to provide reasonable assurance of the safety and effectiveness of the devices. The proposal and reproposal stated that premarket approval is necessary for the devices because the devices present potential unreasonable risks of illness or injury if there are not adequate data to ensure the safe and effective use of the devices. The preamble to the December 20, 1994, final rule (59 FR 65475) classifying the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis and the interarticular disc prosthesis (interpositional implant) into class III advised that the earliest date by which PMA's or notices of completion of PDP's for the devices could be required was June 30, 1997, or 90 days after issuance of a rule requiring premarket approval for the devices.

In the **Federal Register** of January 6, 1989 (54 FR 550), FDA issued a notice of intent to initiate proceedings to require premarket approval for 31 class III preamendments devices. Among other items, the notice described the factors FDA takes into account in establishing priorities for proceedings under section 515(b) of the act (21 U.S.C. 360e(b)) for issuing final rules requiring that preamendments class III devices have approved PMA's or declared completed PDP's. FDA updated its priorities in a preamendments class III strategy document made public through a **Federal Register** notice of availability published on May 6, 1994 (59 FR 23731). Though the above TMJ

prostheses were not included in the lists of devices identified in the notice and the strategy paper, using the factors set forth in these documents, FDA has determined that the total TMJ prosthesis identified in § 872.3940 (21 CFR 872.3940), the glenoid fossa prosthesis identified in § 872.3950 (21 CFR 872.3950), the mandibular condyle prosthesis identified in § 872.3960 (21 CFR 872.3960), and the interarticular disc prosthesis identified in § 872.3970 (21 CFR 872.3970) have a high priority for initiating a proceeding to require premarket approval because the safety and effectiveness of these devices has not been established by valid scientific evidence as defined in 21 CFR 860.7. Moreover, FDA believes that insufficient information exists to identify the proper materials or design for the total TMJ, the glenoid fossa, and the mandibular condyle prostheses.

In the **Federal Register** of July 17, 1997 (62 FR 38231), FDA issued 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 the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis, and the interarticular disc prosthesis (interpositional implant). 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 these devices to meet the premarket approval requirements of the act, and the benefits to the public from use of the devices (62 FR 38231 at 38233). The July 17, 1997, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's findings. Under section 515(b)(2)(B) of the act, FDA also provided an opportunity for interested persons to request a change in the classification of the above devices based on new information relevant to its classification. Any petition requesting a change in the classification of the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis, and the interarticular disc prosthesis (interpositional implant) was required to be submitted by August 1, 1997. The comment period closed on October 15, 1997.

B. FDA's Intention to Reclassify the Temporary Mandibular Condyle Prosthesis

FDA received a reclassification petition, dated April 30, 1996 (Docket No. 96P–0253/CP–1), from Howmedica Leibinger, Inc., requesting the agency to reclassify from class III into class II the mandibular condyle prostheses (§ 872.3960) that are intended for temporary reconstruction of the mandibular condyle in tumor resection patients. Consistent with the act and the regulation, FDA referred the petition to the Panel for its recommendation on the requested change in classification. Based on its review of the new data and information contained in the reclassification petition, the Panel recommended, during its February 12, 1997, open meeting, that the temporary mandibular condyle prosthesis for temporary reconstruction of the mandibular condyle in patients who have undergone resective procedures to remove malignant or benign tumors, requiring the removal of the mandibular condyle, be reclassified from class III to class II. The Panel believed that class II with special controls, including a guidance document, patient registries, and labeling addressing certain identified issues, would provide a reasonable assurance of safety and effectiveness.

On the basis of its review and the Panel's recommendation, FDA now believes that the use of the temporary mandibular condyle implant for temporary reconstruction of the mandibular condyle in tumor resection patients does not present a potential unreasonable risk of illness and injury, and that special controls would provide reasonable assurance of the safety and effectiveness of the device. The scope of Howmedica Leibinger's reclassification petition does not encompass all of the intended uses included in the current description of the mandibular condyle prosthesis in § 872.3960. The reclassification requested is limited to the intended use of implantation into the human jaw for temporary reconstruction of the mandibular condyle in patients who have undergone resective procedures to remove malignant or benign tumors, requiring mandibular condyle removal. Therefore, FDA intends to grant this reclassification petition. The agency also intends to propose reclassifying from class III into class II the mandibular condyle prostheses implanted temporarily for such a limited purpose, identifying this subset of devices as the temporary mandibular condyle prosthesis. For the other uses of the mandibular condyle prosthesis for patients with temporomandibular joint dysfunction, or trauma patients, in which the device would be implanted for a much longer period of time for the purpose of permanent reconstruction, the device will remain in its current class (class III), as it is possible to place a device in a dual classification status. For clarity, FDA intends to identify the devices used for the latter purpose (permanent reconstruction) as the permanent mandibular condyle.

II. Summary and Analysis of Comments and FDA's Response

The agency received four comments in response to the proposed rule. These comments were submitted by three manufacturers and distributors of TMJ implants, and a professional dental organization.

1. One comment referenced the reclassification petition, as described in section I.B of this document, citing the February 12, 1997, recommendation of the Dental Products Panel to reclassify from class III into class II the temporary mandibular condyle implant that is intended for temporary reconstruction of the mandibular condyle in tumor resection patients.

As noted previously, FDA intends to propose reclassification of such devices into class II for certain temporary uses. Accordingly, the agency is excluding such temporary uses under § 872.3960(c)(2) of this final rule. The agency is excluding any mandibular condyle prosthesis that is intended to be implanted in the human jaw for temporary reconstruction of the mandibular condyle in patients who have their mandibular condyle removed during resective procedures to remove malignant or benign tumors from the requirement of premarket approval set forth in § 872.3960(c)(1).

2. Two comments objected to the class III classification for metallic condylar prostheses, and other cobalt-chrome and cobalt-chrome/polymethylmethacrylate TMJ implants, claiming that such TMJ devices do not present a potential unreasonable risk of injury and that sufficient information exists to address their safety and effectiveness through special controls.

FDA has responded already to such materials-related issues in the December 20, 1994, final classification rule (59 FR 65475 at 65476).

3. One of the previous comments also objected to the type of scientific evidence proposed by FDA for the PMA's to be submitted for TMJ prostheses, in terms of prospective randomized well-controlled clinical trials using adequate controls. The manufacturer/distributor advocated that valid scientific evidence can be obtained from any of the sources recognized in the Code of Federal Regulations, and that other sources of appropriate data are available than controlled clinical studies.

FDA agrees that there is a variety of evidence that may be included as valid

scientific evidence. In reviewing PMA's, FDA will consider a variety of evidence in determining safety and efficacy. FDA also agrees that the use of randomized concurrent controls in the clinical study of patients that require total joint replacement may not always be appropriate.

4. One comment strongly supported the FDA proposal to require a PMA or a notice of completion of a PDP for these devices. The favorable comment emphasized that this action ''* * * would enhance the agency's ability to scrutinize and control these devices both before and after they enter the medical marketplace, and thereby better serve the needs of TMJ patients and the public.''

III. Final Rule

Under section 515(b)(3) of the act, FDA is adopting the proposed findings as published in the preamble to the proposed rule and is issuing this final rule to require premarket approval of the TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis (intended for permanent reconstruction), and the interarticular disc prosthesis (interpositional implant).

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 total TMJ prosthesis, glenoid fossa prosthesis, mandibular condyle prosthesis (intended for permanent reconstruction), or interarticular disc prosthesis (interpositional implant) that was in commercial distribution before May 28, 1976, or that have been found by FDA to be substantially equivalent to such devices on or before March 30, 1999. An approved PMA is required to be in effect for any such devices on or before 180 days after FDA files the application or a declared completed PDP within 90 days after FDA files a notice of completion. Any total TMJ prosthesis, glenoid fossa prosthesis, mandibular condyle prosthesis (intended for permanent reconstruction) or interarticular disc prosthesis (interpositional implant) that was not in commercial distribution before May 28, 1976, or that FDA has not found, on or before March 30, 1999, to be substantially equivalent to such devices that were in commercial distribution before May 28, 1976, are required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for a total (TMJ) prosthesis, glenoid fossa prosthesis, mandibular condyle prosthesis (intended for permanent reconstruction), or interarticular disc prosthesis (interpositional implant) is not filed on or before March 30, 1999, 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 under 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 the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis (intended for permanent reconstruction), and the interarticular disc prosthesis (interpositional implant). Further, FDA concludes that investigational total TMJ prosthetic devices, glenoid fossa prosthetic devices, mandibular condyle prosthetic devices (intended for permanent reconstruction), and interarticular disc prosthetic (interpositional implant) devices are significant risk devices as defined in § 812.3(m) and advises that as of the effective date of the regulations in §§ 872.3940(c), 872.3950(c), 872.3960(c)(1), and 872.3970(c), respectively, requirements of the IDE regulations regarding significant devices will apply to any clinical investigations of any of these devices. For any total TMJ prosthesis, glenoid fossa prosthesis, mandibular condyle prosthesis (intended for permanent reconstruction), or interarticular disc prosthesis (interpositional implant) that is not subject to a timely filed PMA or notice of completion of a PDP, an IDE must be in effect under § 812.20 on or before March 30, 1999, or distribution of the device for investigational purposes must cease. FDA advises all persons currently sponsoring a clinical investigation involving the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis (intended for permanent reconstruction), or the interarticular disc prosthesis (interpositional implant) to submit an IDE application to FDA no later than March 1, 1999, to avoid the interruption of ongoing investigations.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

The agency has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354) (as amended by subtitle D of the Small Business Regulatory Fairness Act (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4)). 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. Because PMA's for these devices could have been required by FDA as early as June 30, 1997, and manufacturers have been aware since December 20, 1994, that these devices are class III devices that would be subject to premarket approval, and because firms that distributed these devices prior to May 28, 1976, or whose devices have been found to be substantially equivalent to the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis (intended for permanent reconstruction), and the interarticular disc prosthesis (interpositional implant), will be permitted to continue marketing these TMJ devices during FDA's review of the PMA or the notice of completion of the PDP, 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 in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872—DENTAL DEVICES

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

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.3940 is amended by revising paragraph (c) to read as follows:

§ 872.3940 Total temporomandibular joint 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 March 30, 1999, for any total temporomandibular joint prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a total temporomandibular joint prosthesis that was in commercial distribution before May 28, 1976. Any other total temporomandibular joint prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

3. Section 872.3950 is amended by revising paragraph (c) to read as follows:

§ 872.3950 Glenoid fossa 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 March 30, 1999, for any glenoid fossa prosthesis that was in commercial distribution before May 28, 1976, or that has on or before March 30, 1999, been found to be substantially equivalent to a glenoid fossa prosthesis that was in commercial distribution before May 28, 1976. Any other glenoid fossa prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

4. Section 872.3960 is amended by revising paragraph (c) to read as follows:

§ 872.3960 Mandibular condyle prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* (1) Except as described in paragraph (c)(2) of this section, a PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any mandibular condyle prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a mandibular condyle prosthesis that was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

(2) No effective date has been established of the requirement for premarket approval for any mandibular condyle prosthesis intended to be implanted in the human jaw for temporary reconstruction of the mandibular condyle in patients who have undergone resective procedures to remove malignant or benign tumors, requiring the removal of the mandibular condyle. See § 870.3 of this chapter.

5. Section 872.3970 is amended by revising paragraph (c) to read as follows:

§ 872.3970 Interarticular disc prosthesis (interpositional implant).

* * * * *

(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 March 30, 1999, for any interarticular disc prosthesis (interpositional implant) that was in commercial distribution before May 28, 1976, or that has on or before March 30, 1999, been found to be substantially equivalent to an interarticular disc prosthesis (interpositional implant) that was in commercial distribution before May 28, 1976. Any other interarticular disc prosthesis (interpositional implant) shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: November 23, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–34483 Filed 12–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 658

[FHWA Docket No. 98–3467]

RIN 2125–AE36

Truck Size and Weight; National Network; North Dakota

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: This document modifies the National Network for commercial motor vehicles by adding a route in North Dakota. The National Network was established by a final rule on truck size and weight published on June 5, 1984, as since modified. This rulemaking adds one segment to the National Network as requested by the State of North Dakota.

DATES: This rule is effective January 29, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Klimek, Office of Motor Carrier Information Management and Analysis (202–366–2212), or Mr. Charles Medalen, Office of the Chief Counsel (202–366–1354), Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

Internet users can access all comments received by the U.S. DOT Dockets, Room PL–401, by using the universal resource locator (URL): http://dms.dot.gov. It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202)512–1661. Internet users may reach the **Federal Register**'s home page at: http://www.nara.gov/fedreg and the Government Printing Office's database at: http://www.access.gpo.gov/nara.

Background

The National Network of Interstate highways and federally-designated routes, on which commercial vehicles with the dimensions authorized by the Surface Transportation Assistance Act of 1982 (STAA), 49 U.S.C. 31111, 31113–31114, may operate, was established by a final rule published in the **Federal Register** on June 5, 1984 (49 FR 23302), as subsequently modified. These highways are located in each State, the District of Columbia, and Puerto Rico. Routes on the National Network are listed in appendix A of 23 CFR Part 658.

Procedures for the addition and deletion of routes are outlined in 23 CFR 658.11 and include the issuance of a notice of proposed rulemaking (NPRM) before final rulemaking.

In accordance with these procedures, the State of North Dakota, under authority of the Governor, requested the addition of one segment to the National Network. The segment requested is