seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 10, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–17971 Filed 7–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0253]

Medispec, Ltd.; Premarket Approval of Econolith™ Extracorporeal Shock Wave Lithotripter

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Medispec Ltd., Rockville, MD, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Medispec Ltd., Econolith™ Lithotripter. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 7, 1997, of the approval of the application.

DATES: Petitions for administrative review by August 11, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Russell P. Pagano, Center for Devices and Radiological Health (HFZ–472), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION: On December 26, 1995, Medispec Ltd., Rockville, MD, 20850, submitted to CDRH an application for premarket approval of the Econolith™ Lithotripter. The device is an extracorporeal shockwave lithotripter and is indicated for use in the noninvasive fragmentation of upper urinary tract stones between 5 and 20 millimeters in size.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On April 7, 1997, CDRH approved the application by a letter to the applicant from the Deputy Director, Clinical and Review Policy, the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 11, 1997 file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 10, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–17973 Filed 7–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0166]

Johnson and Johnson Interventional Systems Co.; Premarket Approval of PALMAZ-SCHATZ™ Balloon-Expandable Stent

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Johnson and Johnson Interventional Systems Co., Warren, NJ, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of PALMAZ-SCHATZ™ Balloon-Expandable Stent. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 2, 1994, of the approval of the application. In addition, the PALMAZ-SCHATZ™ Balloon-Expandable Stent requires tracking under the act as amended by the Safe Medical Devices Act of 1990.

DATES: Petitions for administrative review by August 11, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Bram D. Zuckerman, Center for Devices and Radiological Health (HFZ–450),

Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On December 7, 1990, Johnson and Johnson Interventional Systems, Co., Warren, NJ 07059, submitted to CDRH an application for premarket approval of PALMAZ-SCHATZ™ Balloon-Expandable Stent. The PALMAZ-SCHATZ™ Balloon-Expandable Stent is indicated for use in a group of selected patients eligible for balloon angioplasty (see Individualization of Treatment, which is available for examination at the Dockets Management Branch (address above)) with symptomatic ischemic heart disease due to discrete (length less than 15 millimeter (mm)), *de novo* native coronary artery lesions with a reference vessel diameter in the range of 3 to 4 mm. In this patient population, stenting the coronary artery produces a larger luminal diameter, maintains arterial patency, and reduces the incidence of restenosis at 6 months as compared with balloon angioplasty. The stent, however, represents a permanent implant into the coronary artery. One year and longer followup is not well characterized.

On May 3, 1994, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On August 2, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 11, 1997 file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: May 29, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–17975 Filed 7–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NLM Online Application Packet

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: NLM Online Application Packet. *Type of Information Collection Request:* Extension of OMB No. 0925–0223. Expires 08/31/97. *Need and Use of Information Collection:* The NLM uses the information provided by individuals and institutions for MEDLARS online system user code assignments and invoices for system use. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; businesses or other for profit; State or local governments; Federal agencies; Non-profit institutions; Small businesses or organizations. *Type of Respondents:* Organizations, Health Care Providers, Students. The annual reporting burden is as follows: *Estimated Number of Respondents annually:* 1,800. *Estimated Number of Responses per Respondent:* 1: *Average Burden Hours Per Response:* 0.0833 hours; and *Estimated Total Annual Burden Hours Requested:* 149.94. *The annualized cost to respondents is estimated at:* $1,499. There are no capital costs to report. There are no operating or maintenance costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION:

To request additional information on the proposed collection of information or to obtain a copy of the data collection instrument, contact Carolyn Tilley, Head, Medlars Management Section, BSD, LO, NLM, NIH, Building 38A, Room 4N–04, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll free number (301) 402–1076. You may also e-mail your request to: carolyn__tilley@ccmail.nlm.nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.