provided no new information that supports his assertion that the risks posed by these devices are of a magnitude or frequency that is different than those considered by FDA in 1989 in classifying these devices into class I. Moreover, the agency searched its Medical Device Reporting (MDR) data bases in order to ascertain the extent of reported problems or adverse incidents associated with these types of devices. The search for reported events during the period from 1985 to 1997 revealed that not only are the rates of reported problems extremely low, but that the problems are the same type previously reported and considered by FDA and the Panels.

Accordingly, FDA believes, on the basis of the same information considered and the same reasons stated in the 1989 classification regulation, as well as the examination of MDR reports for these devices from 1985 to 1997, that the risks to the public health posed by these devices are low and that class I provides a reasonable assurance of the safety and effectiveness of these devices.

Furthermore, FDA does not agree with the petitioner's claim that the issuance of voluntary and mandatory standards by certain foreign countries evidences the need for a designation of class II with performance standards. The existence of performance standards in other countries for a certain device is not the statutory criterion under the act for the issuance of mandatory performance standards, or a designation of class II.

Under section 513(a)(1)(B) of the act, a device is to be classified in class II if it is a device that cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance. Therefore, the relevant inquiry to determine whether a device should be classified as class II and be subject to performance standards, is not whether there could be performance standards but whether class I controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

On the basis of information described above concerning the risks associated with ostomy pouches and accessories, FDA believes that these devices are appropriately in class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

The petitioner presented insufficient new information, in the form of valid scientific evidence, to determine that special controls described in section 513(a)(1)(B) of the act, in addition to the general controls applicable to all devices, are necessary to provide reasonable assurance of the device's safety and effectiveness for its intended use. FDA, therefore, is denying the petition.

Dated: June 27, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–17972 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–0259]

Kensey Nash Corp.; Premarket Approval of the Angio-Seal™ Hemostatic Puncture Closure Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Kensey Nash Corp., Exton, PA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Angio-Seal™ Hemostatic Puncture Closure Device. 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 September 30, 1996, 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: Christopher M. Sloan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On October 28, 1993, Kensey Nash Corp., Exton, PA 19341, submitted to CDRH an application for premarket approval of the Angio-Seal™ Hemostatic Puncture Closure Device. The device is a vascular hemostasis device and is indicated for use in closing and in reducing time to hemostasis at the femoral arterial puncture site in patients who have undergone diagnostic angiography or percutaneous transluminal coronary angioplasty (PTCA) procedures using an 8F or smaller procedure sheath.

On May 8, 1995, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 30, 1996, 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 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: 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),