relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, notice of participation, and request for hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for hearing is not made in the required format or with the required reports, the Commissioner will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: June 19, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–17977 Filed 7–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93P–0355]

Gastroenterology-Urology Devices; Denial of Request for Change in Classification of the Ostomy Pouch and Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; denial of petition.

SUMMARY: The Food and Drug Administration (FDA) is denying the petition submitted by Abraham L. Lastnik (hereinafter referred to as the petitioner) to reclassify the ostomy pouch and accessories from class I into class II. The agency is denying the petition because there is no new information, in the form of valid scientific evidence, that general controls currently used in the production of these devices are not sufficient to assure the safety and effectiveness of the devices. This notice also summarizes the basis for the agency's decision.

EFFECTIVE DATE: July 10, 1997.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–5072.

SUPPLEMENTARY INFORMATION:

I. Classification and Reclassification of Devices Under the Medical Device Amendments of 1976

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), as amended by the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA's classification of a device is determined by the amount of regulation necessary to provide reasonable assurance of the safety and effectiveness of a device. Except as provided in section 520(c) of the act (21 U.S.C. 360j(c)), FDA may not use confidential information concerning a device's safety and effectiveness as a basis for reclassification of the device from class III into class II or class I.

Under the amendments, devices were classified into class I (general controls) if there was information showing that the general controls of the act were sufficient to provide reasonable assurance of safety and effectiveness; into class II (performance standards) if general controls were insufficient to provide reasonable assurance of safety and effectiveness, but there was sufficient information to establish a performance standard that would provide such assurance; and into class III (premarket approval) if there was insufficient information to support placing a device into class I or class II, and the device was a life-sustaining or life-supporting device or was for a use that is of substantial importance in preventing impairment of human health, or if the device presented a potential unreasonable risk of illness or injury.

FDA has classified most generic types of devices that were on the market before the date of the amendments (May 28, 1976) (generally referred to as preamendments devices) under the procedures set forth in section 513(c) and (d) of the act through the issue of classification regulations into one of these three regulatory classes. Under section 513(c) and (d) of the act, FDA secures expert Panel recommendations on initial device classifications for generic types of devices. FDA then considers the Panel's recommendations and, through notice and comment rulemaking, issues classification regulations.

Devices introduced into interstate commerce for the first time after May 28, 1976, are by statute automatically classified into class III under section 513(f) of the act. These devices may be reclassified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Those devices that FDA finds to be substantially equivalent to a class I or II generic type of device are thereby classified in the same class as the predicate device.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. Section 513(e) of the act provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based on ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person.

The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when a device was originally classified, as well as information not

presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, *supra*, 422 F.2d at 951.) However, regardless of whether data before the agency are old or new data, the ''new information'' on which any reclassification is based is required to consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available in accordance with section 520(c) of the act. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of premarket approval applications.

II. Reclassification Under the Safe Medical Devices Act of 1990

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) further amended the act to change the definition of a class II device. Under the SMDA, class II devices are those devices for which there is insufficient information to show that general controls themselves will provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance, including the issuance of a performance standard or other special controls, such as postmarket surveillance, patient registries, guidelines, and other appropriate actions necessary to provide such assurance of the device. Thus, the definition of a class II device was changed from ''performance standards'' to ''special controls.''

III. Background

In the **Federal Register** of November 23, 1983 (48 FR 53012 at 53023), FDA issued a final rule classifying the ostomy pouch and accessories into class I (§ 876.5900 (21 CFR 876.5900)). Section 876.5900 describes the device as follows:

An ostomy pouch and accessories is a device that consists of a bag that is attached to the patient's skin by an adhesive material and that is intended for use as a receptacle for collection of fecal material or urine following an ileostomy, colostomy, or ureterostomy (a surgically created opening of the small intestine, large intestine, or the ureter on the surface of the body). This generic type of device and its accessories includes the ostomy pouch, ostomy adhesive, the disposable colostomy appliance, ostomy collector, colostomy pouch, urinary ileostomy bag, urine collecting ureterostomy bag, ostomy drainage bag with adhesive, stomal bag, ostomy protector, and the ostomy size selector, but excludes ostomy pouches which incorporate arsenic-containing compounds.

In the **Federal Register** of January 23, 1981 (46 FR 7633), the agency had initially proposed that the devices be classified into class II. The proposal stated that the devices were reviewed by the Gastroenterological/Urological Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel. Although the latter two Panels recommended classification of the ostomy pouch and accessories into class I, the agency agreed with the Gastroenterological/Urological Device Classification Panel recommendation to classify the devices into class II, and proposed classification accordingly. The Panels' recommendations, among other things, addressed the issues of allergenic materials, inadequate fit allowing liquid feces to contact skin, and malposition or slipping of the appliance with pressure against a protruding stoma. In addition, the Panels determined that the device is not an implant nor is it life sustaining or life supporting.

The agency received one comment on the proposed classification of the ostomy pouch and accessories. The comment effectively refuted the arguments used by the Gastroenterological/Urological Device Classification Panel in recommending the devices be classified into class II, and the comment suggested that the devices be classified into class I, instead. In response to the comment, based upon the best information available at that time, and based upon the original recommendations of the General Hospital and Personal Use Device Classification Panel and the General and Plastic Surgery Device Classification Panel, the agency determined to place ostomy devices into class I.

In the **Federal Register** of June 12, 1989 (54 FR 25042), the agency exempted the ostomy pouch and accessories from the requirements of premarket notification, determining that ''the manufacturer's submissions of premarket notifications are unnecessary for the protection of the public health and that review of such notifications by the agency will not advance FDA's public health mission.'' Though the ostomy pouch and accessories were exempted from premarket notification, they were not exempted from the requirements of the current good manufacturing practice regulations of 21 CFR part 820 or other general adulteration or misbranding petitions.

Subsequently, the agency received a petition dated August 30, 1993, submitted by the petitioner requesting that the ostomy pouches and accessories be reclassified into class II.

IV. Agency Decision

The petition stated that it was inappropriate for the agency to classify the devices into class I based, in part, on a single comment submitted by a manufacturer of ostomy accessories, because the manufacturer did not have sufficient information regarding the magnitude or frequency of device related problems. Furthermore, the petitioner states that, ''because ostomy prostheses are in constant contact with tissues that are normally retained within the body cavity, they would be expected to present the same risks * * * as [device] implants.'' These risks include adverse tissue reaction, problems with inadequate fit or improper size, and the potential for toxic systemic effects. The petitioner also claims that the issuance of voluntary and mandatory standards by certain foreign countries evidences the need for performance standards, and that there is sufficient information available to issue such performance standards. The petition asserts that classification into class II and performance standards would eliminate or reduce risks and shortcomings associated with these devices.

FDA recognizes that section 513(e) of the act provides that for a preamendments device for which reclassification is sought, FDA may secure a recommendation concerning the reclassification from the Panel, which had made a recommendation on the initial classification of the device. FDA did not, however, refer this petition to the Panel because the petitioner did not present new information to warrant reconsideration of these devices by a Panel.

Based on its review of the information contained in the petition, the agency finds that the petition raises the same issues previously evaluated by the device classification Panels and FDA when issuing the 1989 final rule classifying ostomy pouches and accessories into class I. The petitioner

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