

Dated: January 22, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-3205 Filed 2-6-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98M-0050]

American Medical Systems Inc.; Premarket Approval of the UroLume™ Endourethral Prostatic for Prostatic Obstruction Secondary to Benign Prostatic Hypertrophy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by American Medical Systems Inc., Minnetonka, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the UroLume™ Endourethral Prostatic for Prostatic Obstruction Secondary to Benign Prostatic Hypertrophy (BPH). After reviewing the recommendation of the Gastroenterology-Urology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 11, 1997, of the approval of the application.

DATES: Petitions for administrative review by March 11, 1998.

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: James P. Seiler, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194.

SUPPLEMENTARY INFORMATION: On May 6, 1996, American Medical Systems Inc., Minnetonka, MN 55343, submitted to CDRH an application for premarket approval of the UroLume™ Endourethral Prostatic for Prostatic Obstruction Secondary to BPH. The device is intended to relieve prostatic obstruction secondary to BPH in men at least 60 years of age, or men under 60 years of age who are poor surgical

candidates, and whose prostates are at least 2.5 centimeters in length.

On January 16, 1997, the Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On April 11, 1997, 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 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 March 11, 1998, 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: October 17, 1997.

Joseph A. Levitt,

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

[FR Doc. 98-3206 Filed 2-6-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Final Special Factors for Grants for Residency Training and Advanced Education in the General Practice of Dentistry Programs for Fiscal Year 1998

Grants for Residency Training and Advanced Education in the General Practice of Dentistry Programs are authorized under section 749, Title VII of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Public Law 102-408, dated October 13, 1992.

Final Special Factors

In determining the funding of approved applications, the Secretary will consider the following Special Factors:

Community linkages-this special factor may be addressed by the establishment of academic-community linkages, in particular linkages between the training program and underserved populations or communities. Documentation of such linkages should include verification that at least 20% of residents' training time occurs in one or more underserved settings. Memoranda of agreement and letters of support from the community settings involved should be included in the appropriate appendix of the application.

Establishment of new PGY-1 training positions-to address the recommendations of expert panels such as the Institute of Medicine and Pew Commission on Health that a year of post-doctoral training be available for all dental graduates, and that the majority of these positions be in general dentistry programs. This special factor may be addressed by the establishment of new postgraduate year-one (PGY-1) training positions, either through the establishment of a new program or the expansion of an existing program. An