

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: March 4, 1997.

Joseph A. Levitt,

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

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[Docket No. 97M-0122]

Xillix Technologies Corp.; Premarket Approval of Xillix LIFE-Lung Fluorescence Endoscopy System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Hogan and Hartson, Washington, DC, U.S. representative for Xillix Technologies Corp., Richmond, B.C., Canada, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Xillix LIFE-Lung Fluorescence Endoscopy System. After reviewing the recommendation of the Ear, Nose, and Throat Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 19, 1996, of the approval of the application.

DATES: Petitions for administrative review by May 1, 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: Kirby J. Cooper, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080.

SUPPLEMENTARY INFORMATION: On December 21, 1995, Hogan and Hartson, Washington, DC, U.S. representative for Xillix Technologies Corp., Richmond, B.C. Canada, submitted to CDRH an application for premarket approval of Xillix LIFE-Lung Fluorescence Endoscopy System. The device is a fluorescence endoscopy system and is indicated for use as an adjunct to white light bronchoscopy, using an Olympus BF-20D bronchoscope, to enhance the physician's ability to identify and locate bronchial tissue, suspicious for

moderate/severe dysplasia or worse, for biopsy and histologic evaluation in the following patient populations:

1. Patients with known or previously diagnosed lung cancer; and
2. Patients with suspected lung cancer including: (a) Patients with Stage I completely resected lung cancer, with no evidence of metastatic disease, who are at risk for secondary disease; and (b) patients suspected of having lung cancer because of clinical symptoms such as positive sputum cytology, hemoptysis, unresolved pneumonia, persistent cough, or positive x-ray.

On June 11, 1996, the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 19, 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 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 May 1, 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: March 4, 1997.

Joseph A. Levitt,

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

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Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 35, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.