

Time and Dates: 1 p.m.-5 p.m. August 3, 1995.

Place: National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Atlanta, Georgia 30345.

Status: Closed.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcements 328, 432, and 461, entitled Cooperative Agreements for Prevention Centers/National Center for Chronic Disease Prevention and Health Promotion—General Special Interest Projects, Panel Number 2.

The meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92-463.

Contact Person for More Information:

James E. Barrow, Deputy Director, Office of Surveillance and Analysis, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, m/s K30, Atlanta, Georgia 30345. Telephone 404/488-5269.

Dated: June 28, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-16514 Filed 7-5-95; 8:45 am]

BILLING CODE 4163-18-M

Food and Drug Administration

[Docket No. 95M-0179]

Summit Technology, Inc.; Premarket Approval of Excimed® UV200LA and SVS Apex (Formerly the OmniMed) Excimer Laser Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Summit Technology, Inc., Waltham, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Excimed® UV200LA and the SVS Apex Excimer Laser Systems. After addressing the concerns of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on March 10, 1995, of the approval of the application.

DATES: Petitions for administrative review by August 7, 1995.

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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Debra Y. Lewis, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2018.

SUPPLEMENTARY INFORMATION: On

February 20, 1992, Summit Technology, Inc., Waltham, MA 02154, submitted to CDRH an application for premarket approval of the Excimed® UV200LA and the SVS Apex Excimer Laser Systems. The excimer laser in the two systems delivers pulses at 193 nanometers wavelength. The excimer laser is indicated for use in the following Phototherapeutic Keratectomy procedures which treat superficial pathology located in the anterior 100 microns of the cornea, where the proposed treatment area is at least 400 microns in thickness, and where other less invasive treatments have failed or are not possible, such as contact lens intolerance. This indication is limited to patients with decreased visual acuity or symptoms of pain and discomfort of sufficient severity to cause disability for the patients with any of the following conditions: (1) Superficial corneal dystrophies (granular, lattice, and Reis-Buckler's); (2) epithelial basement membrane dystrophy; (3) irregular corneal surfaces (secondary to Salzmann's degeneration, keratoconus nodules and other irregular surfaces); and (4) corneal scars and opacities (post-traumatic, post-surgical, post-infectious and secondary to pathology).

On March 21, 1994, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended conditional approval of the application. The concerns of the panel have been adequately addressed by Summit Technology, Inc., in subsequent submissions to FDA. On March 10, 1995, 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 part 12 (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 § 10.33(b) (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 7, 1995, 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 26, 1995.

Joseph A. Levitt,

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

[FR Doc. 95-16624 Filed 7-5-95; 8:45 am]

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