

[Docket No. 96M-0274]

Summit Technology, Inc.; Premarket Approval of SVS Apex (Formerly the Omnimed) Excimer Laser System for Photorefractive Keratectomy (PRK)**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 SVS Apex (formerly the OmniMed) Excimer Laser System. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of October 20, 1995, of the approval of the application.

DATES: Petitions for administrative review by September 16, 1996.

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: Debra Y. Lewis, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-3623.

SUPPLEMENTARY INFORMATION: On October 12, 1993, Summit Technology, Inc., Waltham, MA 02154, submitted to CDRH an application for premarket approval of the SVS Apex (formerly the OmniMed) Excimer Laser System. The excimer laser in the Systems delivers pulses at 193 nm wavelength. The excimer laser is indicated for a 6.0 mm ablation zone photorefractive keratectomy (PRK) in subjects with 1.5 to 7.0 diopters of myopia and astigmatism \leq 1.5 diopters. On October 20, 1995, 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 October 20, 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 September 16, 1996, 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: August 1, 1996.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96-20855 Filed 8-14-96; 8:45 am]

BILLING CODE 4160-01-F

Health Resources and Services Administration**Advisory Council; Notice of Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month September 1996:

Name: Council on Graduate Medical Education.

Date and Time: September 11, 1996, 8:30 a.m.-5:00 p.m.; September 12, 1996, 8:30 a.m.-4:00 p.m.

Place: Omni Shoreham Hotel, Empire Room, 2500 Calvert Street, NW., Washington, DC 20008.

This meeting is open to the public.

Agenda: The agenda will include discussion, reports and recommendations in the following areas: minorities in medicine; geographic distribution/medical education consortia; physician competencies in managed care; and IMG entry and participation in the physician workforce.

Anyone requiring information regarding the subject should contact F. Lawrence Clare, M.D., M.P.H., Deputy Executive Secretary, telephone (301) 443-6326, Council on Graduate Medical Education, Division of Medicine, Bureau of Health Professions, Health Resources and Service Administration, Room 9A-27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Agenda items are subject to change as priorities dictate.

Dated: July 9, 1996.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 96-20820 Filed 8-14-96; 8:45 am]

BILLING CODE 4160-15-P

National Institutes of Health**National Center for Research Resources; Notice of Meeting of the National Advisory Research Resources Council and Its Planning Subcommittee**

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Research Resources Council (NARRC), National Center for Research Resources (NCRR). This meeting will be open to the public as indicated below. Attendance by the public will be limited to space available.

This meeting will be closed to the public as indicated below in accordance with provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or