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 (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 procedures and 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), 360(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.

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...