

JAN 27 1999

K983100

TAB E

510(k) SUMMARY

KaVo KEY Laser 1242

This 510(k) summary of safety and effectiveness for the KaVo KEY Laser 1242 is submitted in accordance with the requirements of SMDA 1990 and follows guidance from the Office of Device Evaluation concerning the organization and content of a 510(k) summary.

Applicant: KaVo America Corporation
340 East Main Street
Lake Zurich, IL 60047

Address (Manufacturer): KaVo Dental GmbH
Bahnhofstr. 20
D-8847 Warthausen
Biberach
GERMANY

Contact Person: Mr. Douglas Cochrane
Product Manager, KaVo KEY Laser 1242
KaVo America Corporation
340 East Main Street
Lake Zurich, IL 60047

Telephone: 800-323-8029
847-550-6800
847-550-6825 (Fax)

Preparation Date: July 1998

Device Trade Name: KaVo KEY Laser 1242

Common Name: Erbium:YAG surgical laser

Classification Name: Surgical Laser

Class: Class II

Legally marketed predicate devices: SEO TriLase; Laserscope Er:YAG, Premier Centauri

Description of Device: The KaVo KEY Laser 1242 is an Er:YAG laser operating at 2.94 microns with energy output up to 500 mJ.

Intended Use: The KaVo KEY Laser 1242 is intended for the incision, excision, ablation, and vaporization of soft tissue in oral and maxillofacial surgery and dentistry.

Performance Data: The specifications and intended uses of the KaVo KEY Laser 1242 are the same or very similar to those of the claimed predicate devices. There are no significant differences between the KaVo KEY Laser 1242 and the claimed predicates in design or under conditions of intended use.

The notification included an extensive bibliography and discussions of specific articles in support of the claim for equivalence.

Because of this, performance data were not required.

CONCLUSION: Based on the foregoing, KaVo America Corporation believes that the KaVo KEY Laser 1242 is substantially equivalent to cited legally marketed predicate devices.



JAN 27 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Doug Cochrane
Product Manager
KaVo America Corporation
340 East Main Street
Lake Zurich, Illinois 60047

Re: K983100
Trade Name: KaVo KEY Laser 1242
Regulatory Class: II
Product Code: GEX
Dated: December 3, 1998
Received: December 7, 1998

Dear Mr. Cochrane:

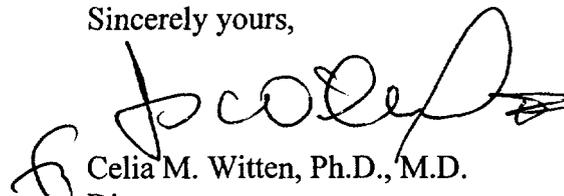
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "C. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TAB D1

510(k) Number (if known): K983100

Device Name KaVo KEY Laser 1242

Indications For Use:

The KaVo KEY Laser 1242 is intended for the incision, excision, cutting, ablation, and vaporization of soft tissue in oral and maxillofacial surgery and dentistry. This includes the following:

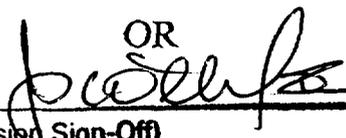
- Surgery (oral and dental) on soft tissue
- Aphthae (herpes, decubitus)
- Incision for drainage of abscesses
- Frenectomy, incision on frenulum of the cheek
- Excision of fibromas and flap fibromas
- Gingivectomy in the case of hyperplasias of the gingiva or excision of hyperplasias
- Preprosthetic surgery, flabby alveolar ridge, vestibuloplasty, exposure of implants, hyperplasias, epulides, papillomas, fibromatoses, benign growths
- Removal of diseased or inflamed tissue in the periodontal pocket (sulcular debridement)

KaVo proposes that the KaVo KEY Laser 1242 be labeled as a prescription device. This labeling will be included in manuals and other information distributed in the United States.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR


Over-The-Counter-Use

(Division Sign-Off)
Division of **General Restorative Devices**
510(k) Number K983100