K030146

SECTION 10

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the KaVo K·E·Y Laser 1242 and KaVo K·E·Y Laser 1243+ is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary. This summary encompasses new hard and soft tissue indications for use for the KaVo K·E·Y Laser 1242 and for the substantial equivalence of the KaVo K·E·Y Laser 1243+ to the KaVo K·E·Y Laser 1242 (or KaVo K·E·Y II Laser).

Applicant: KaVo America

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Lake Zurich, IL 60045

Manufacturer: KaVo Dental GmbH
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Biberach
GERMANY D-8847

Contact Person: Ms. Jennifer Pottala
New Product Manager

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Preparation Date: December 2002
(of the Summary)

Device Name: KaVo K·E·Y Laser 1243+

Common Name: Laser Surgical Instrument; Er:YAG laser

Classification: 21 CFR 878.4810
Product Code: GEX
Panel: 79

Predicate devices: KaVo K.E.Y Laser 1242

Device description: The KaVo K·E·Y Laser 1243+ is an erbium laser which emits its energy at 2.94 microns. The laser consists of a cabinet, foot switch, fiber optic and hand pieces, and a software controlled user/laser interface.

Indications: The KaVo K·E·Y Laser 1243+ and KaVo K·E·Y Laser 1242 are 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)
Tooth preparation to obtain access to the root canal
Pulpotomy
Pulp extirpation
Pulpotomy as an adjunct to root canal therapy
Root canal debridement and cleaning

The KaVo K·E·Y Laser 1243+ and KaVo K·E·Y Laser 1242 are intended for ablation and vaporization of hard tissue in dentistry. The uses include:

Removal of carious tissue
Enamel etching
Cavity preparation
Removal of subgingival calculi in periodontal pockets

The KaVo K·E·Y Laser 1242 and KaVo K·E·Y Laser 1243+ are also labeled as a prescription device for distribution within the United States: "CAUTION: Federal (US) law restricts the use of this device to licensed professionals."

Performance Data: The indication for the removal of subgingival calculus was supported by the results of in vitro, in vivo, and the results of a well-controlled clinical investigation. SEM examination of surfaces provided assurance that the root surfaces were not unduly damaged by the laser energy and laboratory tests demonstrated that fibroblasts would/could adhere to the laser-treated surface in numbers and types comparable or superior to surfaces scaled or planed by other methods.

The results of a well-controlled clinical study with a 2-year follow-up provided evidence that the Er:YAG, i.e., the KaVo K·E·Y Laser 1242, produced equivalent or superior results when compared to mechanical removal/planing of subgingival calculus from the roots of teeth. Objective criteria were measured and recorded at 3-, 6-, 12-, and 24 months and the

results were statistically analyzed. The clinical data demonstrated that the KaVo KEY II laser performed as designed in the clinical study and that the clinical results achieved were equivalent or better than those achieved in the control (mechanical removal of subgingival calculi) group.

The remaining indications for use are based on comparisons of specifications and performance characteristics of the KaVo K·E·Y Laser 1243+ and the KaVo K·E·Y Laser 1242 and do not require performance data.

KaVo notes that there are no unique applications, indications, materials, or specifications presented herein. For all the soft tissue indications for use, the KaVo K·E·Y· 1242 and KaVo K·E·Y· 1243+ are substantially equivalent to each other and to several Er:YAG laser systems and diode laser systems cleared by the FDA.

KaVo notes that there are no unique applications, indications, materials, or specifications presented herein. For all the hard tissue indications for use, the KaVo K·E·Y· 1242 and KaVo K·E·Y· 1243+ are substantially equivalent to each other and to several Er:YAG laser systems cleared by the FDA.

The KaVo K·E·Y· 1242 and KaVo K·E·Y· 1243+ are substantially equivalent to several available established dental laser products and endodontic files driven by rotary handpieces. The KaVo K·E·Y· 1242 and KaVo K·E·Y· 1243+ perform the same indications for use through the same cutting modalities as other laser devices and endodontic files.

KaVo believes that the in vitro, in vivo, and clinical data provide reasonable assurance that the KaVo K·E·Y Laser 1242 and KaVo K·E·Y Laser 1243+ are substantially equivalent to curets when used to remove subgingival calculus.

CONCLUSION: Based on the information in this notification KaVo America believes that KaVo K·E·Y Laser 1243+ is substantially equivalent to the KaVo K·E·Y Laser 1242 and that the indications for use statement, with the new indications for use, i.e., removal of subgingival calculi for periodontal pockets and use in root canal procedures, is appropriate for both.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

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Washington, D. C. 20004

AUG 3 2005

Re: k030146
Trade/Device Name: KaVo KEY Laser (1242 and 1243+)
Regulation Number: 21 CFR 878.4810
Regulation Name: Soft tissue dental laser
Regulatory Class: II (two)
Product Code: NVK
Dated: June 14, 2005
Received: June 14, 2005

Dear Mr. Heller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K030146

Device Name: KaVo K*E*Y Laser Models 1242 (KEY II) and 1243+ (KEY III)

Indications For Use: The KaVo K*E*Y Laser Models 1243+ and 1242 are 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)
Tooth preparation to obtain access to the root canal
Pulpotomy
Pulp Extirpation
Pulpotomy as an adjunct to root canal therapy
Root canal debridement and cleaning

The KaVo K*E*Y Laser Models 1243+ and 1242 are intended for ablation and vaporization of hard tissue in dentistry. The uses include:

Removal of carious tissue
Enamel Etching
Cavity preparation
Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curretage

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for mxm
Division of General, Restorative and Neurological Devices

510(k) Number K030146

Indications for Use (continued)

510(k) Number: K030146

Device Name: KaVo K*E*Y Laser Models 1242 (KEY II) and 1243+ (KEY III)

The KaVo K*E*Y 1243+ will be labeled as a prescription device when distributed within the United States. The KaVo K*E*Y Laser 1242 is labeled as a prescription device (K983100 and K000805).

CAUTION: Federal (US) law restricts the use of this device to licensed professionals.

US

OPERATING INSTRUCTIONS

A 1 User information

The KEY Laser 1243 is a dental treatment device according to ISO 74 94.

A 1.1 Meaning of the pictograms

Situation which may lead to danger, damage to material or operating faults if the instructions are ignored.

Important information for operator and engineer.

A 1.2 Important information

The operating instructions must be read by the user prior to commissioning, in order to avoid incorrect operation and other damage.

Duplication and distribution of the operating instructions and assembly instructions (OI / AI) / engineer's instructions (EI) require KaVo's prior consent.
All technical data, information and properties of the device described in these instructions have been compiled to the best of our knowledge and according to the latest available intelligence before going to press.

Modifications and improvements to the product as a result of new technical developments are possible. This does not imply any right to upgrading.

KaVo assumes no responsibility for damage due to

- external effects (poor quality of the media or poor installation),
- use of incorrect information,
- improper use,
- improperly performed assembly, commissioning and repairs.

Only technicians who have successfully completed KEY Laser 1243 training are permitted to assemble, prepare and maintain the KEY Laser 1243. If this is not complied with, the approvals will become null and void.

Only qualified laser technicians should calibrate this laser. The warranty may be voided if anyone other than a qualified technician attempts to calibrate this laser.

It is advisable to use original KaVo spare parts.

Safety

The information in Section A 2 Laser Safety must be followed.

Registration

The respective national regulations for operation must be complied with.

A 1.3 Purpose and mode of operation

The KEY Laser 1243 should be used only for dentistry.

The current application manual is always available from KaVo.

A 1.4 Indications for use statements

Indications for use statement (soft tissue)

Indications For Use:
The KaVo KEY Laser 1243 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
- Preposthetic surgery; flabby alveolar ridge, vestibuloplasty, exposure of implants, hyperplasias, epulides, papillo mas, fibromatoses, benign growths
- Removal of diseased or inflamed tissue in the periodontal pocket (sulcular debri dement)

Indications for use statement (hard tissue)
Indications For Use:
The KaVo KEY Laser 1243 is intended for ablation and vaporization of hard tissue in dentistry. The uses include the:

- removal of carious lesions
- enamel etching
- cavity preparation.

Indications for use (periodontal treatment)
- removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage.

Clinical studies have not been conducted to demonstrate the long term safety and effectiveness of the Key 3 Laser for periodontal scaling.