K103753

FEB 15 2011

510(k) Summary
for
Sirona Dental Systems SIROLaser Advance

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 32 94

Date Prepared: August 4, 2010

2. DEVICE NAME

Proprietary Name: SIROLaser Advance

Models: SIROLaser Advance
SIROLaser Xtend upgraded
SIROLaser Xtend
FONALaser

Common / usual name: Dental Soft Tissue Laser
Classification Names: Laser instrument, surgical, powered

3. PREDICATE DEVICE

SIROLaser Advance, Biolase iLase

4. INTENDED USE

Models: Sirolaser Advance and SIROLaser Xtend Upgrade

Intended Use:
Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue

Indications for Use:

K103753

Marginal and interdental gingival and epithelial lining of free gingiva;frenectomy;frenotomy; biopsy; operculectomy; Implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue ; laser assisted flap surgery; debridement of deseased epithelial lining ; incisions and draining of abscesses; tissue retraction for impressions ; papillectomy ; vestibuloplasty ; excision of lesions ; exposure of unerupted/partially erupted teeth ; removal of hyperplastic tissues ; treatment of aphthous ulcers ; leukoplakia ; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; Fibroma removal; Gingival incision and excision; Treatment of canker sores; herpetic ulcers of the oral mucosa; Laser soft tissue curettage; Reduction of gingival hypertrophy.

Models: SIROLaser Xtend and FONALaser

Intended Use:
Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue

Indications of use:
marginal and interdental gingival and epithelial lining of free gingiva; frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue ; incisions and draining of abscesses; tissue retraction for impressions ; papillectomy ; vestibuloplasty ; excision of lesions ; exposure of unerupted/partially erupted teeth ; removal of hyperplastic tissues ; treatment of aphthous ulcers ; leukoplakia ; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; Fibroma removal; Gingival incision and excision; Treatment of canker sores; herpetic ulcers of the oral mucosa; Laser soft tissue curettage; Reduction of gingival hypertrophy.
Models: Sirolaser Advance and SIROLaser Xtend Upgrade

5. DEVICE DESCRIPTION

K103753

The SIROLaser Advance is a Diode Laser System for dental soft tissue surgery. The system is comprised of the laser unit with handpiece, laser fibers of different diameters, bendable tips, and a wireless foot control.

The SIROLaser Advance has the following basic functions

- Ability to emit laser radiation either in continuous wave mode (cw) or chopped mode
- Setup and display of treatment parameters:
  - power,
  - treatment time,
  - chop frequency
  - duty cycle
- Selection of predetermined settings for different indications
- Upgradeable firmware

6. Basis for Substantial Equivalence

The Sirona Dental Systems SIROLaser Advance Device is substantially equivalent to Sirona SIROLaser Advance (K0092660) and Biolase iLase. Performance testing to validate the safety and effectiveness of the SIROLaser Advance includes electrical safety, electromagnetic compatibility, and validation testing of both hardware and software functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sirona Dental Systems GmbH
% TUV SUD America Inc.
Mr. Olaf Teichert
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

FEB 15 2011

Re: K103753
Trade/Device Name: SIROLaser Advance
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 02, 2011
Received: February 04, 2011

Dear Mr. Teichert:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

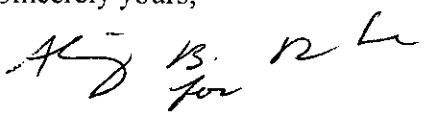
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103753

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: SIROLaser Advance
Models: Sirolaser Advance and SIROLaser Xtend Upgrade
Indications for Use:
Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue;marginal and interdental gingival and epithelial lining of free gingiva;frenectomy;frenotomy; biopsy; operculectomy; Implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue ; laser assisted flap surgery; debridement of deseased epithelial lining ; incisions and draining of abscesses; tissue retraction for impressions ; papillectomy ; vestibuloplasty ; excision of lesions ; exposure of unerupted/partially erupted teeth ; removal of hyperplastic tissues ; treatment of aphthous ulcers ; leukoplakia ; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; Fibroma removal; Gingival incision and excision; Treatment of canker sores; herpetic ulcers of the oral mucosa; Laser soft tissue curettage; Reduction of gingival hypertrophy; .

Device Name: SIROLaser Advance
Models: SIROLaser Xtend and FONALaser
Intra- and extra-oral surgery including incision excision hemostasis, coagulation and vaporization of soft tissue; marginal and interdental gingival and epithelial lining of free gingiva; frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue ; incisions and draining of abscesses; tissue retraction for impressions ; papillectomy ; vestibuloplasty ; excision of lesions ; exposure of unerupted/partially erupted teeth ; removal of hyperplastic tissues ; treatment of aphthous ulcers ; leukoplakia ; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; Fibroma removal; Gingival incision and excision; Treatment of canker sores; herpetic ulcers of the oral mucosa; Laser soft tissue curettage; Reduction of gingival hypertrophy;

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)
Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices