

DEC - 3 2009

**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: October 30, 2009

**2. DEVICE NAME**

Proprietary Name: SIROLaser Advance  
Common / usual name: Dental Soft Tissue Laser  
Classification Names: Laser instrument, surgical, powered

**3. PREDICATE DEVICE**

SIROLaser, Kavo Gentle Ray 980, Ivoclar Odyssey Navigator, Ceramoptec  
Ceralas D15

**4. INTENDED USE**

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

Indications for use are the following applications: marginal and interdental gingiva 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 diseased 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, sulcular debridement (removal of diseased or inflamed soft tissue, in the periodontal pocket), pulpotomy, pulpotomy as adjunct to root canal therapy.

## 5. DEVICE DESCRIPTION

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 (K053161), Kavo Gentle Ray 980 (K072262), Ivoclar Odyssey Navigator (K062258) and Ceramoptec Ceralas D15 (K983058, K991891). 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.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

DEC - 3 2009

Sirona Dental Systems GmbH  
% Mr. Fritz Kolle  
Fabrikstrasse 31  
D-64625 Bensheim  
Germany

Re: K092660

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: October 30, 2009

Received: November 03, 2009

Dear Mr. Kolle:

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 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

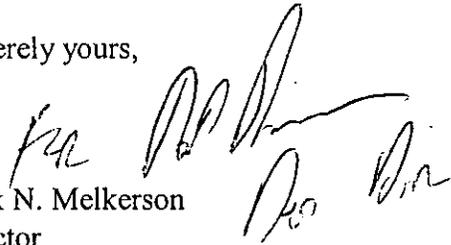
Page 2 – Mr. Fritz Kolle

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/cdrh/mdr/> 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/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

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**INDICATIONS FOR USE**

510(k) Number (if known):

Device Name: SIROLaser Advance

Indications for Use:

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

Indications for use are the following applications: marginal and interdental gingiva 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 diseased 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, sulcular debridement (removal of diseased or inflamed soft tissue, in the periodontal pocket), pulpotomy, pulpotomy as adjunct to root canal therapy.

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)  
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Karen S. Bay for NRO  
Division Sign-Off)

Sirona Dental Systems special 510(k)  
SIROLaser Advance

August 26, 2009  
Division of Surgical, Orthopedic,  
and Restorative Devices Page vii

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