Section 5: 510(k) Summary

The assigned 510(k) number is: K081652

Company: Elexxion AG
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78315 Radolfzell, Germany
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AUG 28 2008

Contact: Dr. Holger Ernst

Date Prepared: June 9th, 2008

Proprietary Names: Claros nano Dental Laser System

Classification Name: Surgical Powered Laser Instrument

Common Name: Dental Diode Laser

Classification Code: • Claros nano - Class II, 21 CFR 878.4810, GEX

Predicate Devices: Biolase LaserSmile, #K030539
Elexxion Claros,#K063152

Device Description: The Claros nano Dental Laser System is a variant of the Claros Dental Laser System. It is a portable laser that uses a gallium aluminum arsenide 810 nm diode laser module to provide optical energy via a contact fiber optic delivery system. Claros nano is used for multiple soft tissue, periodontal, and teeth whitening applications.

The Claros nano Dental Laser System is comprised of the following main components:
• a light/ laser system console (including software, a display panel and controls);
• delivery devices;
• one or more handpieces; and
• protective eye wear.

Intended Use: Please refer to Attachment 1

Performance Data: The Claros nano Dental Laser System complies with the following standards:
• IEC 60601-1:1988+A1:1991+A2:1995
• IEC 60601-2-22:1995
• IEC 60825-1:1993+A1:1997+A2:2001
• 21 CFR 1040.10 and 1040.11

Substantial Equivalence:	The Claros nano Dental Laser System (and accessories) shares the same or similar indications for use, principles of operation, overall technical and functional capabilities, and therefore is substantially equivalent for use in general and plastic surgery and dentistry for surgical applications to the predicate device identified.
Conclusion:	The Claros nano Dental Laser System (and accessories) is substantially equivalent to previously cleared dental devices and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Elexxion AG
% Dr. Holger Ernst
Head of R&D Technology
Schützenstrasse 84
78315 Radolfzell, Germany

AUG 28 2008

Re: K081652
Trade/Device Name: Claros nano Dental Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 9, 2008
Received: June 12, 2008

Dear Dr. Ernst:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

K081652

510(k) Number (if known):

Device Name: Claros nano Dental Laser System

Indications for Use:

Dental Soft Tissue Indications Including Pulpal Tissues*
Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including: Excisional and incisional biopsies, Exposure of unerupted teeth, Fibroma removal, Frenectomy, Frenotomy, Gingival troughing for crown impressions, Gingivectomy, Gingivoplasty, Gingival incision and excision, Hemostasis and coagulation, Implant recovery, Incision and drainage of abscesses, Leukoplakia, Operculectomy, Oral papillectomies, Pulpotomy, Pulpotomy as an adjunct to root canal therapy, Reduction of gingival hypertrophy, Soft tissue crown lengthening,
Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa, and Vestibuloplasty.

*For use on adult and pediatric patients

Laser Periodontal Procedures
Laser soft tissue curettage, Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket, Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium, Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)

Tooth Whitening
Laser assisted whitening/bleaching of teeth, Light activation for bleaching materials for teeth whitening

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

K081652

Prescription Use ___XX____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) 510(k) Number (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)