OCT 15 2008 K082945

Section 5 – 510(k) Summary

I. General Information

Submitter:	OroScience, Inc. 2275 East Bayshore Road, Suite 106 Palo Alto, CA 94303
Contact Person:	Phil Houle Vice President R&D, Operations
Summary Preparation Date:	July 2, 2008

II. Names

Device Names:	Curative980 Diode Lasers (and delivery device accessories)
Primary Classification Names:	Laser Powered Surgical Instruments (and Accessories)

III. Predicate Devices

- Quanta System Diode Medical Laser – 808, 940, or 980 nm (K072034)
- Hoya ConBio DioDent MICRO - 980 nm (K063384)
- Biolitec Ceralas 980 nm / SmilePro 980 (K050824)
- Laser Dental Innovations LiteSaber™ 2000 (K993942)
- Laser Dental Innovations StarLite 2006 (K052604)
- B&W Tek, Inc. BWF-5 Medical Laser Series (K062363)

IV. Product Description

The Curative980 Diode Lasers are comprised of the following main components:

- Main console containing the major electrical components, including:
  - Control Touch-Screen Display Panel including touch controls;
  - 980 nm treatment laser (aluminum gallium arsenide (AlGaAs) solid state laser diode);
  - 650 nm aiming beam diode laser;
  - Delivery device fiber-optic connector port;
  - Emergency stop switch;
  - Remote interlock connector (External door interlock connector);
  - Connector ports for the footswitch and power cord;
  - Handpiece holder (attaches to the top of the laser system console);
  - Fiber Spool (secures and organizes the optical fiber) attaches to the side of the main console;
- Footswitch;
- Medical grade power cord;
- Delivery Devices:
  - Optical Fibers - Reusable, cleanable, sterilizable optical fibers;

- Handpieces - Reusable, cleanable, sterilizable handpieces;
- Handpiece Tips - Disposable single-use tips;

- Accessories:
  - Safety Glasses
- Tools:
  - Optical Fiber Striper;
  - Optical Fiber Cleaver.

V. Indications for Use

The Curative980 Diode Lasers and the delivery accessories that are used with them to deliver laser energy are intended for use in the medical specialty of dental surgery.

The Curative980 Diode Lasers (and the delivery accessories that are used with them to deliver laser energy) is indicated for use in a variety of applications requiring incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue in the medical specialty of dental surgery.

VI. Rationale for Substantial Equivalence

The Curative980 Diode Lasers share the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Curative980 Diode Lasers are substantially equivalent to the predicate devices.

VIII. Conclusion

The Curative980 Diode Lasers were found to be substantially equivalent to the predicate devices.

The Curative980 Diode Lasers share identical indications for use, similar design features, and functional features with, and thus are substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2008

OroScience, Inc.
% A Worden Consulting
Ms. Anne Worden
3637 Bernal Avenue
Pleasanton, California 94566

Re: K082445
Trade/Device Name: OroScience Curative980 Diode Lasers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use ing eneral and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 9, 2008
Received: October 10, 2008

Dear Ms. Worden:

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 Statement - Continued

510(k) Number (if known): **K08**

Device Name: **OroScience Curative980 Diode Lasers**

Indications for Use:

The Curative980 Diode Lasers and the delivery accessories that are used with them to deliver laser energy are intended to deliver laser energy for incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue in the medical specialty of dental surgery as follows:

Dental Surgery
Indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissue (intraoral and extraoral) including marginal and inter-dental gingival and epithelial lining of free gingival and the following specific indications:

- Biopsy
- Excisional and incisional biopsies
- Excision of lesions
- Exposure of unerupted/partially erupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingival troughing
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Hemostasis of donor site
- Implant recovery
- Removal of granulation tissue
- Laser assisted flap surgery

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)
Division of General, Restorative, and Neurological Devices

510(k) Number k082445

Indications for Use Statement - Continued

510(k) Number (if known): **K08**

Device Name: **OroScience Curative980 Diode Lasers**

Indications for Use - Continued:

Dental Surgery - Continued

- Debridement of diseased epithelial lining
- Treatment of aphthous ulcers
- 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)
- Laser soft tissue curettage
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Operculectomy
- Incision and drainage of abscess
- Oral papillectomies; papillectomy
- Removal of hyperplastic tissues
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Reduction of bacterial level (decontamination) and inflammation
- Soft tissue crown lengthening; crown lengthening
- Tissue retraction for impressions
- Leukoplakia
- Vestibuloplasty
- Light activation of bleaching materials for teeth whitening.
- Laser-assisted bleaching/whitening for teeth

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