Section III. 510(k) Summary

Diode Laser Therapy System

NOV 17 2010

China Daheng Group, Inc.

(As required by 21 CFR 807.92)

K Number: K102669

1. Date Prepared: July 26, 2010

2. Sponsor Information

China Daheng Group, Inc.
15/F, North Section, Daheng Scitech Mansion,
No.3 Suzhou Street, Haidian District, Beijing,100080, China

Contract Person: Yu Wang, Sales Director
Phone: +86-10-82782668 - 243
Fax: +86-10-72782669

3. Submission Correspondent

Ms. Diana Hong
Mr. Tarzan Wang
Shanghai Mid-Link Business Consulting Co., Ltd
P.O. BOX 237-023
Shanghai, 200237, China
Tel: +86-21-64264467
Fax:+86-21-64264468
Email: Diana.hong@mid-link.net

4. Proposed Device Information

Device Common or Usual Name: Dental diode laser;
Device Trade or Proprietary Name: Diode Laser Therapy System
Classification Name: Laser instrument, Surgical, Powered
Regulation Number: 21 CFR 878.4810
Product Code: GEX
Panel: 878 General and Plastic Surgery
Model: DenLase-810/7; DenLase-980/7

5. Predicate Device

Odyssey Navigator Diode Laser (K062258)
Manufactured by IVOCLAR VIVADENT, INC.

KaVO GENTLEray 980 （K072262）
Manufactured by KAVO AMERICA

Picasso (K083142)
Manufactured by AMD LASERS, LLC

SiroLaser(K053161)
Manufactured by SIRONA DENTAL SYSTEMS GMBH

6. Device Description

Denlase Dental Laser Therapy System are new devices for 510(k) submission and share the similar indication for use and safety compliance, similar design features and functional features with the predicate devices.

The DenLase is a surgical device designed with compactness, portability, reliability and user-friendliness. It provides the operator with a tool for surgical and cosmetic procedures on oral soft tissue. The Denlase utilizes a semiconductor diode with invisible infrared radiation as a laser source (810nm or 980nm). The laser power is delivered to the treatment area via a flexible fiber, which has a handpiece. The emission laser is activated by a footswitch.

The Denlase adopts advanced semiconductor lasers (AlGaAs) and semiconductor refrigeration technology. By laser sent out by optical fiber, it can fast and accurately dispose tissue and lesion. The device includes three operation modes as continuous, single pulse and continuous pulse, and each operation mode is adjustable respectively by three parameter of emitting power, pulse width and pulse interval. The user can save total five groups of operation mode parameter combination under different mode.

Based on this, the Dental Laser Therapy System is laser indicated for use in surgical applications including Pulposis, Periodontal disease, Diseases of oral mucosa, Oral and Maxillofacial Diseases, Salivary gland disease, Cosmetic Dentistry.

Table III-1 Recommendation Clinical Application

Intended	Mode	Recommended Wavelength	Power Length	Power Interval
Abscess	810/7 & 980/7	810nm, 980nm	CW	---
Aphthous Ulcer	810/7 & 980/7	810nm, 980nm	200 μ s	200 μ s
Bleaching	810/7 & 980/7	810nm, 980nm	CW	---
Crown Lengthening	810/7 & 980/7	980nm	50 μ s	200 μ s
Curettage	810/7	810nm	100 μ s	200 μ s
devridement of deseased epithelial lining	980/7	,980nm	100 μ s	200 μ s
Exposure of Underpted teeth	810/7	810nm	50 μ s	200 μ s
Excision/Incisions	810/7 & 980/7	810nm, 980nm	50 μ s	200 μ s
Frenectomy	810/7 & 980/7	810nm, 980nm	100 μ s	200 μ s
Gingivectomy	810/7 & 980/7	810nm, 980nm	50 μ s	200 μ s
Hemostasis	810/7 & 980/7	810nm, 980nm	CW	---
Implant Recovery	810/7 & 980/7	810nm, 980nm	50 μ s	200 μ s
Troughing	810/7 & 980/7	810nm, 980nm	100 μ s	200 μ s
Biopsy	810/7 & 980/7	810nm, 980nm	CW	---
Fibroma	810/7	810nm	CW	---
Gingivoplasty	810/7 & 980/7	810nm, 980nm	CW	---
Herpes	810/7	810nm	200 μ s	200 μ s
Hyperplasia	810/7 & 980/7	810nm, 980nm	CW	---
Pulpotomy as an Adjunct to Root Canal Therapy	810/7 & 980/7	810nm, 980nm	CW	---
Leukoplakia	810/7 & 980/7	810nm, 980nm	200 μ s	200 μ s
Mucoceles	810/7	810nm	CW	---
Partially Erupted Teeth	980/7	980nm	50 μ s	200 μ s
Papillectomy	980/7	980nm	CW	---

Operculectomy	810/7 & 980/7	810nm, 980nm	CW	---
Vestibuloplasty	810/7 & 980/7	810nm, 980nm	CW	---
Pulpotomy	810/7 & 980/7	810nm, 980nm	CW	---
Sulcular debridement	810/7 & 980/7	810nm, 980nm	CW	---
Tooth Whitening/bleaching	810/7 & 980/7	810nm, 980nm	CW	---

7. Intended use

The Diode Laser Therapy System (DenLase-810/7 & DenLase-980/7) is indicated for intraoral use for the following soft tissue applications:

- Incision
- Excision
- Vaporization
- Ablation
- Coagulation.

8. Substantial Equivalence

Denlase Dental Laser Therapy System shares the similar indications for use, design features, functional features, same safety compliance. Therefore the proposed device is **substantially equivalent (SE)** to the predicate devices.

The differences between the subject device and predicate device as following:

Table III-2

Dimension (H×W×D)	19.0×13.0×18.0 cm	9 1/2"×6"×4"	17×26×18cm	15 × 16 × 23cm	87 × 54 × 190 mm
Weight	1.5kg	2.5 lb	3.5 Kg	Less than 2 lb	450 g
Duty Cycle	1: (600000 to 1)	pulsed mode 50% continuous wave 100% (1:1)	1: (200000 to 1)	/	2:1 to 1200:1
Frequency of Pulse	0-10kHz	fixed 10 Hz	2 to 20 kHz	1-10000Hz	/

For the difference of dimension and weight, although the subject device has some differences with the predicates, but the subject device meet the same safety and performance standard with the predicates, so it has the same safety and effectiveness with predicate.
For the difference of duty cycle and frequency of pulse, although the subject device has tiny differences with the predicates, but the subject device meet all performance standard, such as IEC60825-1, IEC60601-2-22, so there are no marked difference with predicates.

9. Testing

Denlase Dental Laser Therapy System is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60825-1: Safety of laser products - Part 1: Equipment classification, requirements and user's guide.
- IEC 60601-2-22: Medical Electrical Equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.
- IEC 60601-1: Medical Electrical Equipment – Part1: General requirements for safety.
- IEC60601-1-2: Medical Electrical Equipment – Part 1: General requirements for safety-2, Collateral Standard: Electromagnetic compatibility – Requirements and tests.
- ISO 10993-5: Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

Non-Clinical Conclusion:

Laboratory testing was conducted to validate and verify that the proposed device, Denlase Dental Laser Therapy System met all design specifications and was substantially equivalent to the predicate device. No Clinical Information is required

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

China Daheng Group, Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

NOV 17 2010

Re: K102669
Trade/Device Name: Diode Laser Therapy System DenLase-810/7; DenLase-980/7
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: November 1, 2010
Received: November 5, 2010

Dear Mr. Devine:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102669

Section II. Indications for Use Statement

NOV 17 2010

510(k) Number: K102669

Device Name: Diode Laser Therapy System
DenLase-810/7;DenLase-980/7

Indications for Use:

The Diode Laser Therapy System (DenLase-810/7 & DenLase-980/7) is indicated for intraoral use for the following soft tissue applications:

- **Incision**
- **Excision**
- **Vaporization**
- **Ablation**
- **Coagulation.**

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 THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBetz DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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