GLOBAL DENTAL DIRECT

510(K) SUMMARY

PRODUCT, CLASSIFICATION NAME
Trade name: Global GDCH - 2000
Common name: Dental unit attached to patient chair
Classification: EIA, Class 1
Regulation number: 872.6640

OWNER & MANUFACTURER
Global Dental Direct Inc.
#4 - 2120 Paramount Crescent
Abbotsford, B.C. Canada V2T 6A5
Phone:604-557-1150
Fax: 604-859-1165
Contact person: Don Temple

UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)
Planmeca USA Inc.
100 North Gary Avenue, Suite A
Roselle, IL 60172
Phone :(630) 529 2300
Fax :(630) 529 1929
Contact person: Bob Pienkowski

INTENDED USE
Global GDCH - 2000 is a dental operative unit attached to a dental patient chair. The dental operative unit is an AC-powered device that is intended to supply power to and serve as a base for other dental devices and accessories. The device also functions to deliver air, water and vacuum to the dental devices/accessories. The device is attached to a dental patient chair, which is intended to properly position a patient to perform different dental procedures. The device is to be operated and used by dentists and other legally qualified professionals.

PRODUCT DESCRIPTION
The Global GDCH - 2000 is a dental operative unit attached to a dental patient chair. The design is very flexible with many functions, both left-handed and right-handed use is easily obtainable. The dentist and assistant are allowed to change their working postures and positions according to the operation to be performed. The versatile swiveling function enables fluent two-handed and four-handed treatment sequences. The unit is equipped with a digital control system with graphical user interface (GUI) to offer ease-of-use.

SUBSTANTIAL EQUIVALENCE
We consider this new product to be similar in design, composition and function to the following device introduced into commercial distribution after Dec 4, 2003:

#K032756 Adec 532 Delivery System

The device has similar technological characteristics (i.e. design, material, energy source, dimensions, weight). The comparison of characteristics supports substantial equivalence. Comparable non-clinical tests have been conducted (such as Encl. 13 – Appendix 8-1 attached from an accredited testing laboratory). Similar Standards (UL 60601-1 and CSA-C22.2 No. 601.1-90 were used in testing of the devices. The end use and user of the Global GDCH 2000 and the Adec unit are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 29 2009

Global Dental Direct, Incorporated
C/O Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K092851
Trade/Device Name: Global GDCH-2000
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: September 15, 2009
Received: September 16, 2009

Dear Mr. Kogoma:

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 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

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital, ~~Infection Control and Dental Devices~~
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GLOBAL DENTAL DIRECT

Indications for Use

510(k) Number K092851

Device Name: Global GDCH - 2000

Indications For Use:

Global GDCH – 2000 is a dental operative unit attached to patient chair. The dental operative unit is an AC-powered device that is intended to supply power to and serve as a base for other dental devices and accessories. The device also functions to deliver air, water and vacuum to the dental devices/accessories. The device is attached to dental patient chair, which is intended to properly position a patient to perform different dental procedures. The device is to be operated and used by dentists and other legally qualified professionals.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092851