K041458

AUG 2 4 2004

Denimed Electrónica
Equipamientos Odontológicos

May 25, 2004

510(k) Summary

Applicant:

Denimed Electrónica
Bv. De Lós Alemanes 3485 B° Los Boulevares
X5022EOG Córdoba-Argentina
Tel & Fax: (0351) 475-0950
Owner/Operator Number: 9063675

Preparer:

Dental Products of USA, Inc.
1460 NW 107 Ave Suite G
Miami, Florida 33172
Tel: 305-640-9894 Fax: 305-477-3206
Contact Person: George Echeverri
Owner/Operator Number: 9034594

Summary Prepared Date:

May 25, 2004

Device Name:

I. *Proprietary Name:* *Mare Dental Operative Unit*
II. *Common/Usual Name:* *Dental Operative Unit*
III. *Classification Name:* *Dental Operative Unit with Accessories*

Predicate Devices:

I. *C 8+ Dental Operative Unit with Accessories, K032543*
II. *Spirit S 1 Dental Operative Unit with Accessories, K962071*

Intended Use:

The Mare Dental Operative Unit with accessories is intended to supply power to and serve as a base for dental devices and accessories. The unit is designed to conveniently position the dentist's dynamic instruments for use during dental procedures. The unit is intended for use in the dental clinic environment and used by trained dentists and/or dental technicians and assistants. The unit delivers air, water and electricity to allow the dental practitioner an intuitive control for all common and normal patient treatment procedures performed in the dental clinic. The Mare unit system is a component of a complete dental treatment suite. Other components are the chair, suction and waste unit and task light. In a fixed location the Mare unit will be connected to an electrical supply, a wastewater trap and an air supply. The Mare Dental Operative Unit with accessories shall be subject to regular operator checks and it will be the responsibility of the dentist or dental therapist to ensure that the apparatus is fully functional before use.

Device Description:

> *The Mare Dental Operative Unit provides connections for five pneumatically operated instruments. The unit can supply air, water and electricity, which may include an air/water syringe, high and low speed handpiece, electric motors, ultrasonic scalers, and dental curing lights, these accessories are not part of the unit.*

The unit provides automatic instrument selection by means of a five way pneumatic valve located in each instrument hanger assembly. The automatic selection takes place when a static air pressure signal is removed from the top of a diaphragm located in the handpiece control block. The Mare Dental Operative Unit consists of the following components:

I. *Patient Treatment Chair: It has two controls; a foot control and a digital pad in the instruments console for all chair positions, auto return system, preset position, emergency stop system and electric cup filler. The entire Mare features an articulating, detachable headrest.*

II. *Cuspidor with Water Unit: The ceramic bowl, cup fillers and the bowl irrigator are detachable. The Mare features a swivel ceramic bowl.*

III. *Dental Light: The Unit features a lamp with two intensity settings.*

IV. *Instruments Console: Features an instruments auto selection system and a master digital control.*

V. *Rolling Chair: Height adjustable backrest and inclination setting.*

Technological Characteristics and Substantial Equivalence:

The Mare Dental Operative Unit with Accessories is substantially equivalent to Sirona Dental Systems C8+ Dental Operative Unit, K032543 and the Spirit S1 Dental Operative Unit, K962071. The Mare unit has the same intended use as the predicates in that they are all used to supply power to, and serve as a base for dental devices and accessories. The components that make up this delivery system in many instances are generic to the dental industry and are made of the same materials utilized by other manufacturers that provide an equivalent product. These materials include; poly vinyl compounds (PVC), polyurethane tubing, stainless steel, painted steel, anodized and plated alloy compounds and ABS plastics which is substantially equivalent to Spirit S1 Operative Unit. The Mare unit system is designed as a dental chair mounted unit and mounts on a two inch steel post. The mechanical safety similarities between the Mare unit and Spirit S1 unit are very similar they both have a safety fuse on the bottom of the unit, as an industry standard. The polyurethane air and water supply lines are connected in a floor mounted metal utility box. The air and water lines have both manual shut off valves and pneumatically controlled automatic shut off valves. The on/off switch located on the control section of the Mare unit, controls the pneumatic valves. The water lines are specially designed for disinfecting, using common bleach/water rinsing without suffering deterioration.

Energy/Water and Air, Used and/or Delivered:

Mare Technical Information		***Spirit S1 Technical Information***	
Voltage:	*110 ó/or 220 Volts*	*Voltage:*	*110 Volts*
Frèquency:	*506/or 60Hz*	*Frequency:*	*50 Hz*
Water Pressure:	*40 psi Kg/cm2*	*Water Pressure:*	*cm2*
Air Pressure:	*5 baró/or 80psi*	*Air Pressure:*	*80 psi*
Air Consumption:	*100 L/min*	*Air Consumption:*	*100 min*
Water Consumption:	*3L/m*	*Water Consumption:*	*2m*

The technological characteristics of the proposed and predicate devices are the same in that they include similar components, and are similar in design, characteristics and mode of operation. Both the proposed and predicate devices include a chair, dentist's instrument board, cuspidor, assistant's board, dental light and footswitches for control of the various components. The Mare unit also includes additional features that do not change the fundamental technology of the device or raise new questions of safety or effectiveness. The Mare unit successfully passed the electrical safety tested per IEC 60601-1/14-12-2000 standards, which meets the safety requirements for medical electrical systems. The Mare unit successfully passed, the DNV (Det Norske Veritas) ISO 9002: 2000 which meets the Quality Management System Standards. The Mare unit is currently being tested for the ETS (European Test Standards).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2004

Denimed Electrónica S.H.
C/O Mr. George Echeverri
Export Sales Director
Dental Products of USA, Incorporated
1460 NW 107 Avenue Suite G
Miami, Florida 33172

Re: K041458
Trade/Device Name: Mare Dental Operative Unit
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: May 25, 2004
Received: August 5, 2004

Dear Mr. Echeverri:

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.

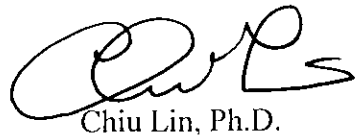
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If know): K041458

Device Name: Mare Dental Operative Unit

Statement of Indications for Use:

Intended Use for the Mare Dental Operative Unit:

The Mare Dental Operative Unit and Accessories is intended for use in general dental applications by providing the dental practitioner a user interface to control operation of the dental chair and attached dental devices.

The system delivers air, water, and electricity to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental office.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 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: K041458