K083347

SYBRON DENTAL SPECIALTIES

DEC 2 4 2008

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: November 2008

Device Name:

- Trade Name - *Impulse 7010 Defibrillator Selectable Loads*
- Common Name - Accessory to Defibrillator Tester
- Classification Name - Defibrillator Tester, per 21 CFR § 870.5325

Devices for Which Substantial Equivalence is Claimed:

- Datrend Systems Inc., *Phase 3Variable Load Module (VLM)*

Device Description:

The *Impulse 7010* Defibrillator Selectable Loads is an optional accessory to the Impulse 7000DP to simulate 25 to 200 Ohm thoracic impedance. Four 50 Ohm resistors are switched in combinations to make series or parallel circuits of 25, 50, 75, 100, 125, 150, 175 and 200 Ohms. Defibrillator output energy is measured by the Impulse 7000DP Defibrillator Tester.

Indication for Use:
The *Impulse 7010* is used to determine that a defibrillator is performing with in its operating specifications by providing multiple loads of 25, 50, 75, 100, 125, 150, 175 and 200 Ohms. The *Impulse 7010* is used in conjunction with the Impulse 7000DP Defibrillator Analyzer.

Substantial Equivalence:
The *Impulse 7010* is substantially equivalent to other legally marketed devices in the United States. The *Impulse 7010* functions in a manner similar to and is intended for the same use as the *Phase 3* Variable Load Module (VLM) marketed by Datrend Systems Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fluke Biomedical
c/o Sybron Dental Specialties, Inc.
Ms. Colleen Boswell
1717 West Collins Ave.
Orange, California 92867

DEC 2 4 2008

Re: K083347
Trade/Device Name: Impulse 7010 Defibrillator Selectable Loads
Regulation Number: 21 CFR 870.5325
Regulation Name: Defibrillator Tester
Regulatory Class: Class II
Product Code: DRL
Dated: November 13, 2008
Received: November 13 2008

Dear Ms. Boswell:

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) 276-0120. 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 Biometrics' (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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: *Impulse 7010 Defibrillator Selectable Loads*

Indications for Use:

The *Impulse 7010* is used to determine that a defibrillator is performing within its operating specifications by providing multiple loads of 25, 50, 75, 100, 125, 150, 175 and 200 Ohms. The *Impulse 7010* is used in conjunction with the Impulse 7000DP Defibrillator Analyzer.

Prescription Use _____ 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 Cardiovascular Devices
510(k) Number K083347