K072114

SYBRON DENTAL SPECIALTIES

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

JAN 28 2008

Submitter:

Sybron Dental Specialties, Inc.
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Orange, California 92867
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Colleen Boswell - Contact Person

Date Summary Prepared: January 2008

Device Name:

- Trade Name –*Impulse 6000D/7000DP*
- Common Name – Defibrillator Tester
- Classification Name – Defibrillator Tester, per 21 CFR § 870.5325

Devices for Which Substantial Equivalence is Claimed:

- Fluke Biomedical, *Impulse 4000*

Device Description:

The *Impulse 6000D/7000DP* is a portable, rechargeable, battery-operated defibrillator tester. The *Impulse 7000DP* also functions as a transcutaneous pacemaker tester. The device's defibrillator input is connected to the output of a defibrillator under test which provides a 50-Ohm test load, approximately the impedance of the human body. The *Impulse 6000D/7000DP* simulates patient electrocardiogram signals to trigger automated defibrillation when a ventricular fibrillation waveform is presented, and the device tests that the automated defibrillator does not advise shock when a normal sinus rhythm electrocardiogram is presented. The energy output delivered by the defibrillator under test is measured. The *Impulse 7000DP* also tests transcutaneous pacemaker outputs by presenting a low level electrocardiogram at various pulse rates and measures the response of the pacemaker under testing rate and amplitude. For pacemaker testing, the device incorporates inputs of 50 to 1500 Ohm impedance test loads. The *Impulse 6000D* is a defibrillator tester only without the pacemaker test option. Both models have 10 electrocardiogram outputs to simulate patient milli-volt level electrocardiogram signals to test combination patient monitors/defibrillators/pacemakers.

The *Impulse 7000DP* has a USB type "B" interface to a PC to allow data download to a PC. It is electrically isolated from the measurement circuitry and allows remote control of the test from a PC. A BNC type connector on the rear panel also allows an oscilloscope to

record the waveform output from the defibrillator under test, attenuated to a lower voltage level, and also electrically isolated from the measurement circuitry. Another BNC connector outputs a higher level signal (greater amplitude) to view the electrocardiogram signal on a second oscilloscope channel.

The accessories for the *Impulse 6000D/7000DP* include an external power supply to operate and re-charge the internal battery. Optional adapters to connect defibrillators marketed by different manufacturers to the standard 4 mm banana style input jacks are available.

Waveform analysis determines the characteristics of a defibrillator discharge pulse. Peak voltage amplitude, current, timing, overall energy and the refractory period of a pacemaker are recorded. Measurement is done by attenuating the high voltage signal to a lower voltage level, which is then input into an analog to digital converter. A digital signal processor calculates the measurements and corrects hardware error sources with mathematical calibration constants for any offset and gain errors.

Indication for Use:

The *Impulse 6000D/7000DP* is used to determine that defibrillators and transcutaneous pacemakers are performing within their performance specifications though the measurement of energy output.

Substantial Equivalence:

The *Impulse 6000D/7000DP* is substantially equivalent to other legally marketed devices in the United States. The *Impulse 6000D/7000DP* functions in a manner similar to and is intended for the same use as the *Impulse 4000* marketed by Fluke Biomedical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 2008

Fluke Biomedical
c/o Ms. Colleen Boswell
Vice President, Regulatory Affairs
Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, CA 92867

Re: K072114
Trade/Device Name: IMPULSE 6000D/7000DP
Regulation Number: 21 CFR 870.5325
Regulation Name: Defibrillator tester
Regulatory Class: Class II (two)
Product Code: DRL
Dated: January 15, 2008
Received: January 16, 2008

Dear Ms. Boswell:

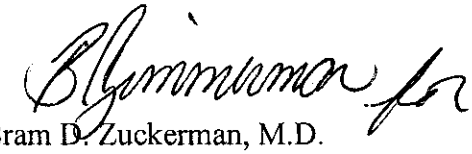
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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,



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: K072114

Device Name: *Impulse 6000D/7000DP*

Indications for Use:

The *Impulse 6000D/7000DP* is used to determine that defibrillators and transcutaneous pacemekers are performing within their performance specifications through the measurement of energy output.

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 Cardiovascular Devices
510(k) Number K072114