510(k) Summary

1. Applicant Information

Submitter:	Huntleigh Healthcare Limited Diagnostic Products Division
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Contact:	Robert McCarthy
Prepared:	May 30th, 2008

2. Device Information

Propriety Name:	Smartsigns Minipulse MP1 and MP1R
Common/Classification Name:	Pulse Oximeter

3. Identification of legally marketed device to which submitter claims equivalence

Predicate Device:	BCI Smiths Medical 3303 Hand Held pulse Oximeter (510(k) No' K945754)

4. New Device Description

The Smartsigns Minipulse MP1 is a hand held, battery powered pulse oximeter used for monitoring pulse rate and saturated oxygen in arterial blood. It is also available as a rechargeable unit (MP1R). The MP1R is supplied with four rechargeable batteries, a Deskstand charger unit and power supply. The MP1R is recharged by docking it on the Deskstand charger unit. The Smartsigns MP1 and MP1R provide audible alarms, a membrane keypad and LED displays to display digital values of heart rate and saturation. Pulse amplitude is displayed by means of a bargraph LED array. The keypad allows the unit to be switched ON and OFF, it also allows the user to set alarm limits for saturation and heart rate.

5. Statement of Intended Use

The Smartsigns Minipulse MP1 and MP1R handheld pulse oximeter is intended for non-invasive continuous or spot check monitoring of functional arterial oxygen saturation (SpO2) and pulse rate. It is intended for use on adult and pediatric patients in hospitals and hospital-type facilities. This device is for prescription use only.
The Smartsigns Minipulse MP1 and MP1R share the same intended use and indications for use as the above referenced predicate device.

6. Summary of Technological Characteristics

The pulse oximetry function is determined by passing two wavelengths of light, one red and one infrared through body tissue to a photodetector. Oxygen saturation calculation is performed on the basis that oxygen rich blood absorbs less red light than oxygen depleted blood. The oximeter function is provided through an OEM oximeter board which uses the same technology found in the legally marketed BCI 3303 pulse oximeter.

7. Brief discussion of the clinical and non-clinical tests

Safety and environmental testing was conducted in accordance with IEC 60601-1: 1988, UL 60601-1: 2006 and EN 60601-1-2: 2001. Electromagnetic compatibility (EMC), electrical, mechanical durability, safety (operator and patient) and temperature/humidity testing have been completed. The results demonstrate that the Smartsigns MP1 and MP1R pulse oximeter is in compliance with the guidelines and standards referenced and that it performs within its specifications and functional requirements.

For oximetry testing a desaturation trial was conducted by the oximeter OEM. The results obtained were within specification. The accuracy of SpO2 and pulse rate have also been verified with in-house testing and comparison to the legally marketed predicate device BCI 3303.

8. Conclusions

Based on these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed device.

This summary on 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA1990 and 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 01 2008

Mr. Robert McCarthy
Design Manager
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35 Portmanmoor Road
Cardiff, South Glamorgan
UNITED KINGDOM CF24 5HN

Re: K081572
Trade/Device Name: Smartsigns Minipulse MP1 and MP1R
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 19, 2008
Received: September 22, 2008

Dear Mr. McCarthy:

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,

Samuel Lin MD for

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 known): _____

Device Name: **Smartsigns Minipulse MP1 and MP1R**

Indications for Use:

The Smartsigns MP1 and MP1R handheld pulse oximeter is intended for non-invasive continuous or spot check monitoring of functional arterial oxygen saturation (SpO2) and pulse rate.

It is intended for use by healthcare professionals for monitoring adult and pediatric patients in hospitals and hospital-type facilities.

The specific medical indications for the use of this device is :

- This device is a prescription device
- This device is re-useable and is intended for spot or continuous measurement
- This device is intended to display oxygen saturation, heart rate and pulse strength or pulsatile signal.
- This device is intended to indicate an alarm if the measured saturation or heart rate are outside user-set alarm limits.

Prescription Use YES (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K081572