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5. 510(k) SUMMARY K 113865

Submitter:	Sharp Corporation 2613-1, Ichinomoto-Cho, Tenri, Nara, Japan 632-8567
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Date Prepared:	*December 22, 2011*
Trade Name:	Sharp Pulse Oximeter Model BM-500(Main Unit) and BM-510 (Sensor)
Common Name:	Pulse Oximeter
Classification Name:	Oximeter
Product Code:	DQA
Classification:	Class II, CFR 820.2700
Predicate Device:	K081285 - Nonin Medical, Inc Onyx II 9560 K001085 - Nonin Medical, Inc Onyx 9500 K053419 - Konica Minolta PULSOX-300/300i
Device Description:	The Sharp Pulse Oximeter is a multi-parameter module comprising of a main unit (BM-500) and the SpO2 Sensor (BM-510) connected via the sensor cord. The device operates continuously to provide spot-check measurements of oxygen saturation and pulse when a patient's finger is inserted into the sensor and the ON button is depressed.
Statement of Intended Use:	The Sharp Pulse Oximeter Model BM-500 and BM-510 is a non-invasive pulse oximeter indicated for use in the spot-check measurement and display of arterial blood oxygen saturation (SpO_2) and pulse rate in hospitals or primary care settings.
Summary of Technological Characteristics:	The Sharp Pulse Oximeter Model BM-500 and BM-510 is uses an optical sensor and transmittance technology to detect changes in the finger's arterial blood and converts the optical signals into electric signals. The main unit then converts the electric signals into numeric data that is displayed on the LCD screen displaying the blood oxygen saturation and pulse.
Summary of Non-Clinical Data:	SpO_2 accuracy and pulse rate accuracy were confirmed by the reference method using the pseudo pattern pulse wave. Electromagnetic compatibility and electrical safety are ensured by testing.

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Summary of Clinical Data:	Two pulse oximeters were placed on 12 subjects and compared to a blood gas analyzer. Hypoxia was induced to different levels of oxyhemoglobin saturation (between 70-100%) by having subjects breathe mixtures of nitrogen, room air, and carbon dioxide. Two hundred data points were plotted and regression analysis was performed. The pulse oximeters demonstrated statistical alignment with the blood gas analyzer SpO_2 results.
Conclusion:	Sharp Corporation considers the Pulse Oximeter Model BM-500 and BM-510 to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and materials, test results, and established medical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Sharp Corporation
C/O Ms. Diane Rutherford
Regulatory Engineer
Ken Block Consulting
1201 Richardson Drive, Suite 280
Richardson, Texas 75080

Re: K113865
Trade/Device Name: Sharp Pulse Oximeter Model BM-500 (Main Unit) and Model BM-510 (SpO_2 Sensor)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: March 6, 2012
Received: March 7, 2012

Dear Ms. Rutherford:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Anthony D. Watson, B.S., M.S., M.B.A.
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: K113865

Device Name: Sharp Pulse Oximeter Model BM-500 (Main Unit) and
Model BM-510 (SpO_2 Sensor)

Indications for Use:

The Sharp Pulse Oximeter Model BM-500 and BM-510 is a non-invasive pulse oximeter indicated for use in the spot-check measurement and display of arterial blood oxygen saturation (SpO_2) and pulse rate in hospital or primary care settings.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(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 CDHR, Office of Device Evaluation (ODE)

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

510(k) Number: K113865