510(K) Summary

K092641

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OCT 2 1 2010

Device Information

Trade Name: Charmcare Tabletop Pulse Oximeter
Regulation Description: Oximeter
Product Code: DQA
Regulation Number: 870.2700
Device Class: Class II

Device Description

The device works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red light; the other is 940 nm, which is ultra red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2. This applicant device of Accuro is the desktop pulse oximeter monitor, which mainly function are measurement, display, alarm, data storage.

Indication for Use

Charmcare Tabletop Pulse Oximeter is portable device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients via finger in hospitals, medical facilities, and subacute environments. Pediatric population in this 510(K) application is defined as 'infant' and 'child' which are ages from 1 month to 12 years according to the guidance 'Premarket Assessment of Pediatric Medical Devices' section IV. Charmcare Tabletop Pulse Oximeter is intended for spot-checking and / or continuous monitoring of patients, the sensor of device is reusable or disposable.

Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- N-395 Pulse Oximeter (K991823) manufactured by Nellcor Puritan Bennett Inc.

Comparison to Predicate Devices

Substantial equivalence to the following legally marketed predicate devices with the same of similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for predicate devices and for the N-395, as well as testing to accepted industry standards. In addition, in-vitro and non-invasive controlled hypoxia studies were conducted to establish the Accuro's accuracy and to ensure that the sensors meet their currently published accuracy specifications with the Accuro.

1) Non-clinical performance test summary – Refer to the "Accuro System Test Form"

• Spo2 test

Method : The sensor of Accuro was connected to the Fluke Index2 Spo2 simulator. As the SpO2 setting value of the simulator changed from 100% to 30% with steps of 2% per minutes. The difference(error) between SpO2 value of simulator and that of Accuro was calculated. This cycle was repeated for Pulse Rate of 60, 150, 250bpm and average time of 2, 4, 8, 12 seconds.

Criteria : SpO2 100~70% : error within ±2% / SpO2 70~30% : error within ±3%

Result : Accuro passed the performance criteria in entire SpO2 range for all the pulse rate and average time modes.

• Pulse Rate test

Method : With SpO2 value of the Index2 simulator fixed to 98%, Pulse Rate of the simulator changed from 250bpm to 30bpm. The difference(error) between the pulse rate value of simulator and that of Accuro was calculated. This cycle was repeated for average time = 2, 4, 8, 12 seconds

Criteria : error within ±2bpm

Result : Accuro passed the performance criteria in entire Pulse Rate range for all average time modes.

• Electrical, mechanical , and environmental tests

For the test methods and acceptance criteria, refer to each test report.

Safety : IEC 6061-1, ISO 9919

Electrical : FCC Part 15, Section 15.109, Class B

Biacompatibility : ISO 10993-10

Result : Accuro passed all criteria

2) Evaluation of the difference between Accuro and N-395 devices

Nellcor N-395 adopts SatSeconds algorithm for alarm management which is to suppress alarm when the SpO2 de-saturation is not too severe or the duration of de-saturation is short. The main purpose of this scheme is to remove the effect of unserious short duration de-saturation 'glitches' and functions as motion filtering.

Similarly, Charmcare Tabletop Pulse Oximeter adopts alarm management system which prevents incorrect alarms caused either by 'glitches' or motion. First, Charmcare Tabletop Pulse Oximeter adopts special type moving average algorithm to remove the effect of glitches in SpO2 or pulse rate. The device takes average from recently acquired samples. The sample values are sorted and samples near the lower or higher limits are filtered before averaging so that the effect of glitch is eliminated. Second, digital signal processing algorithm filters out invalid frequency domain components arising from motion. If the filtering continues over a pre-determined time, the device considers that it is a motion situation. Then, the device suppresses alarms and displays motion indication. In this way, Charmcare Tabletop Pulse Oximeter implements equivalent alarm management and motion filtering functions as the Nellcor N-395 Pulse Oximeter.

3) Summary of the clinical data

The clinical test for Accuro included 10 subjects- 7 women and 3 men. The Accuro oximeter was studied with neonate, adult, disposable, and pediatric sensors (neonate is not included in the intend for use of this device). Healthy non-smoking individuals of age 21-49 were included in the study. The skin colors were composed of 1 dark, 3 medium, and 6 light colors. Some subjects showed low perfusion index for some specific SpO2 ranges, usually below 80%.

The rms error between SaO2 and SpO2 was calculated for each sensor.

For SpO2 70~100%, rms error of each sensor was

Adult Sensor : 1.72 / Disposable Sensor : 2.37 / Pediatric Sensor : 2.61

Overall rms error : 2.21

The test showed that rms errors of disposable sensor and pediatric sensor were slightly bigger than the error limit of performance test stated above (2% for 70~100%). This deviation was mainly due to low perfusion index of some subjects, which resulted in unreliable signal input. Another reason was that the averaging algorithm of the Accuro required settling time of SpO2 values when there was a change in the saturation level. If there was a relatively big change of the saturation level in a short time, a temporary gap between the SpO2 and SaO2 values was caused.

In spite of the adverse events stated above, the rms error of the clinical test was less than or slightly above the performance test criteria of Charmcare, which is 2%. The predicate device N-395 also shows 2% error limit for adults in the SpO2 range from 70% to 100%. According to this comparison, Charmcare pulse oximeter showed substantial equivalence to the predicative device N-395.

Conclusion

The Charmcare pulse oximeter, subject of this submission, constitutes a safe, reliable and effective medical device, meeting all the declared requirements of its intended use. Device presents no safety risks to patients when used as intended. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, Charmcare pulse oximeter and its predicate devices are believed to be substantially equivalent.

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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OCT 2 1 2010

Re: K092641
Trade/Device Name: Charmcare Tabletop Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 17, 2010
Received: October 14, 2010

Dear Ms. Bang:

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.

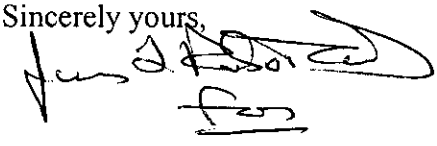
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K092641

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Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 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: K092641