K083079

MAR 5 2009

Section 4 【B】

510(k) Summary

K083079

MAR 5 2009

510(K) SUMMARY

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

1. Submitter's Name: **Quanta Computer Inc.**
BG1 Medical Devices Department

Address: 2F, No. 188, Wen Hwa 2nd Rd.,
Kuei Shan Hsiang, Tao Yuan Shien 33377, TAIWAN

Phone: +886-3-327-2345 #18029

Fax: +886-3-327-2345

Contact: Jason Hung / Title: Specialist 1

2. Device Name :

Trade Name: **Quanta Pulse Oximeter**
Model no.: **Pulse Link 1000 (or QH100)**

Common Name: Pulse Oximeter

Classification name Oximeter

3. DEVICE CLASS The **Quanta Pulse Oximeter , Model no.: Pulse Link 1000 (or QH100)** has been classified as
Regulatory Class: II
Panel: Anesthesiology
Product Code: DQA
Regulation Number: 21CFR 870.2700

4. Predicate Device:

- **Palmsat Pulse Oximeter, Model #2500A (K#050056)** marketed by **NONIN MEDICAL, INC..**
- **OXIMAX Pulse Oximeter , Model #NPB-40 (K#051352)**marketed by **NELLCOR PURITAN BENNETT, INC.**

5. Intended Use: The Quanta Pulse Oximeter , Model no. Pulse Link 1000 (or QH100) is a handheld pulse oximeter with alarm. It is intended to be used by trained healthcare professionals in hospital, hospital type facilities, as well as in the home care environment .

The Pulse Link 1000 Pulse Oximeter is indicated for non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of patients on fingers (forefinger or middle finger).

The Pulse Link 1000 Pulse Oximeter is re-useable. It is indicated for adult patients under no-motion conditions.

6. Device Description:

The **Quanta Pulse Oximeter , Model no.: Pulse Link 1000 (or QH100)** is a digital handheld pulse oximeter that displays numerical values for blood oxygen saturation (%SpO2) and pulse rate. It provide audible and visual alarms for both medium and high priority conditions.

The **Quanta Pulse Oximeter , Model no.: Pulse Link 1000 (or QH100)** will typically operate for 24 hours continuously between alkaline battery replacements. The QH100 Oximeter requires no routine calibration or maintenance other than replacement of alkaline batteries and basic cleaning.

The **Quanta Pulse Oximeter , Model no.: Pulse Link 1000 (or QH100)** determines functional oxygen saturation of arterial hemoglobin (SpO_2) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate. Oxygen saturation and pulse rate values are displayed by LCM monitor. On each detected pulse, the LED indicates the health condition of the patient. If the health condition of the patient is bad (under some specific criteria), the LED will blink red and beeps alarm from the speaker. A sensor disconnect is also indicated by the LED blinking yellow and beeps alarm from the speaker. The remaining energy of the battery is indicated by the marked scale of the battery indicator on the LCM monitor.

7. Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included ISO 9919, IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **Quanta Pulse Oximeter , Model no.: Pulse Link 1000 (or QH100)** has the same intended use and similar technological characteristics as the **Palmsat Pulse Oximeter, Model #2500A (K#050056)** marketed by **NONIN MEDICAL, INC. and OXIMAX Pulse Oximeter , Model #NPB-40 (K#051352)**marketed by **NELLCOR PURITAN BENNETT, INC.**.. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, The **Quanta Pulse Oximeter , Model no.: Pulse Link 1000 (or QH100)** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 5 2009

Quanta Computer Incorporated
C/o Ms. Jennifer Reich
Harvest Consulting Corporation
2904 North Boldt Drive
Flagstaff, Arizona 86001

Re: K083079
Trade/Device Name: Quanta Pulse Oximeter
Regulation Number: 21 CFR 880.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 25, 2009
Received: February 26, 2009

Dear Ms. Reich:

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,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting 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): K083079

Device Name: **Quanta Pulse Oximeter ,**
Model no.: **Pulse Link 1000 (or QH100)**
Quanta Computer Inc.
BG1 Medical Devices Department

Indications For Use:

The Quanta Pulse Oximeter , Model no. Pulse Link 1000 (or QH100) is a handheld pulse oximeter with alarm. It is intended to be used by trained healthcare professionals in hospital, hospital type facilities, as well as in the home care environment .

The Pulse Link 1000 Pulse Oximeter is indicated for non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of patients on fingers (forefinger or middle finger).

The Pulse Link 1000 Pulse Oximeter is re-useable. It is indicated for adult patients under no-motion conditions.

Prescription Use V 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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083079