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EXHIBIT 2
510(k) Summary of Safety and Effectiveness

Meridian Co., Ltd..
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September 18, 2002
Contact: Soorang Lee, R&D Director

1. **Identification of the Device:**
   Proprietary-Trade Name: McPulse Photoelectric Plethysmograph
   Classification Name: Plethysmograph, Photoelectric, Product code JOM
   Common/Usual Name: Photoelectric Plethysomograph

2. **Equivalent legally marketed devices** This product is similar in function to the Novametrix Pulse Oximeter, Model 500 510(k) No. : K853124 Applicant: NOVAMETRIX MEDICAL SYSTEMS INC

3. **Indications for Use (intended use)** : The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.

4. **Description of the Device:** The McPulse Photo-Plethysmograph is intended to be used to measure pulse waveform and heart rate in the finger by lighting a fingertip with combination of infrared LED and photodiode. The measurement probe is an optoelectronic sensor consisted of a light-emitting diode(infrared LED) and a photodiode placed on opposite side as a light receiver. The light from the LED is transmitted through the tissue at the sensor site and a photodiode in the sensor measures the transmitted light and this signal is used to determine how much light was absorbed. This device converts the changes of transmitted light from a photodiode into a waveform and displays a graphic display of the pulse waveform on LCD screen. Pulse rate is measured using the time between successive pulses and displayed digital values on LCD screen. The McPulse system consists of an optoelectronic sensor that is applied to the patient and a microprocessor-based system that processes and displays the measurement. The optoelectronic sensor contains a light-emitting diode(infrared LED) and one photodiode as a light receiver. The light from the LED is transmitted through the tissue at the sensor site. The photodiode in the sensor measures the transmitted light and this signal is used to determine how much light was absorbed..

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart**

Feature	Novametrix Pulse Oximeter, Model 500 (K853124)	McPulse
INDICATION OF USE	measures pulse waveform , SaO_2 and heart rate by photoelectric plethysmograph	measures pulse waveform and heart rate by photoelectric plethysmograph
MODE	Non invasive	Non Invasive
PRACTITIONER USE	Professional use only	Professional use only
DISPLAY	Digital LCD display Analog display	Digital LCD Display
POWER SOURCE	AC(100/120/220/240Vac, 50/60Hz)/ DC(Portable rechargeable battery)	AC (100-240Vac, 50/60Hz)
TYPE OF SENSOR	LED-Photodiode / finger, ear probe, flexible sensor	LED-Photodiode / finger probe
ANATOMICAL SITE	Finger, ear, wrap around	Finger
RECORDER OUTPUTS	pulse waveform Heart rate SaO_2%	pulse waveform Heart rate
HEART RATE RANGE & DISPLAY RESOULTION	25-250bpm 1bpm	30-230bpm 1bpm
SIZE (unit : mm)	228.6(W) x 92.08(H) x254(D)	305.5(W) x 296(H) x 92.5(D)
WEIGHT	Approx. 3.6kg	Approx. 5.5 kg

7. **Conclusion**

After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of Meridian Co. Ltd.. that the McPulse Photoelectric Plethysmograph is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2003

Meridian Co., Ltd,
c/o Mr. Daniel Kamm, P.E.
Regulatory Associate
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K023238
Trade Name: McPulse Photoelectric Plethysmograph
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, pneumatic, or photoelectric plethysmographs
Regulatory Class: Class II (two)
Product Code: JOM
Dated: January 14, 2003
Received: January 15, 2003

Dear Mr. Kamm:

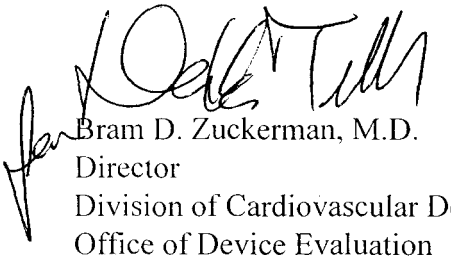
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K023238

Device Name: McPulse Photoelectric Plethysmograph

Indications for Use: The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K023238