K073323

**510(k) Summary**
**Prepared November 23, 2007**

**Submitted by:**

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NOV 2 9 2007

**Contact Person:**

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**Product Name:** SA3000P System

**Common Name:** Pneumatic Plethysmography

**Classification:** JOM; Class II; CFR 21 870.2780

**Predicate Devices:** McPulse by Meridian Co. Ltd.

**Description of Device:** The device is a photoelectric plethysmograph with is used to estimate blood flow in a region of the body using photoelectric measurement techniques

**Intended Use:** The device provides noninvasive measurement of pulse waveform and heart rate by photoelectric plethysmography. The anatomical site for taking the measurement is the left index finger. The device is intended for use with patients age 18 years and older and with a weight of 100 lbs or greater. The device is indicated for use in hospitals, health care clinics and physicians' offices

**Comparison with Predicate Devices:** The SA-3000P is substantially equivalent to the indication for Use and the technological characteristics of the predicate device, the Meridian McPulse device (K023238)

**Performance:**

The device has completed performance testing showing that The functions are substantially equivalent to the predicate In addition the device meets the same safety and performance Standards as the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2007

Medicore Co., Ltd
c/o Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K073323
SA-3000P
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, Pneumatic or Photoelectric Plethysmograph
Regulatory Class: Class II (two)
Product Code: JOM
Dated: November 26, 2007
Received: November 27, 2007

Dear Mr. Job:

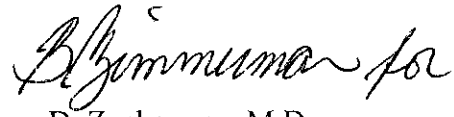
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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 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,



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

Enclosure

510(k) Number (if known): K073323

Device Name: SA3000P

Indications For Use:

The device provides noninvasive measurement of pulse waveform and heart rate by photoelectric plethysmography. The anatomical site for taking the measurement is the left index finger. The device is intended for use with patients age 18 years and older and with a weight of 100 lbs or greater. The device is indicated for use in hospitals, health care clinics and physicians' offices

Prescription Use____X____ OR Over-The-Counter Use _____
(Per 21CFR 801)

(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 Cardiovascular Devices
510(k) Number K073323