MEDTECHS LLC

page 1/1

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the Requirements of Safe Medical Device systems Act 1990 and 21 CFR Sec. 807.92

510(k) Number: K083735

Applicant Information:

FEB 1 8 2009

Date Prepared: November 12, 2008

Name: MTecHS
Division of MedTechs, LLC
Address:
111, Beaver Dam Run
Durham, NC 27703
Phone: 1 877 833 3493

Contact Person: Meghan Ath
Phone Number: 919 619 7657
Fax Number: 215 474 0127
meghan@medtechs.us

Device system Information:

Classification: JOM/ClassII/870.2780
Trade Name: 'ANSHA'
Common Name: Pneumatic Plethysmograph

Substantial Equivalence:

Medicore Co.Ltd. SA 3000P System	K073323
QHRV-1 Health Assessment System	K080884

Reason for submission: Modification – additional features to existing product

Performance: The functions are substantially equivalent to the predicate. In addition the device has undergone performance testing and meets the same safety and performance standards as the predicate.

Intended Use:

ANSHA -QHRV1 has the same intended use as the legally marketed predicate device systems. The ANSHA -QHRV1 is intended for non-invasive measurement of pulse waveform by photoelectric plethysmography and heart rate by electrocardiograph. The device is for use in out-patient departments of hospitals, healthcare clinics and physician practices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2009

MEDTECHS, LLC.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th St NW
Buffalo, MN 55313

Re: K083735
Trade/Device Name: ANSHA - QHRV1
Regulation Number: 21 CFR 870.2780
Regulation Name: Plethysmograph, photoelectric, pneumatic or hydraulic
Regulatory Class: Class II
Product Code: JOM, DPS
Dated: January 26, 2009
Received: January 28, 2009

Dear Mr. Job:

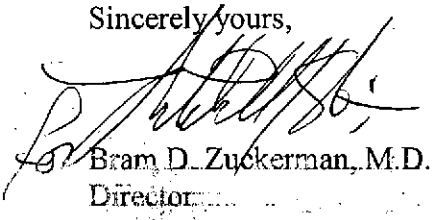
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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



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

Enclosure

Indications for Use

510K Number (if known) K083735

Device system Name: ANSHA - QHRV1

Indications for Use: ANSHA (QHRV1) is intended for noninvasive measurements of pulse waveforms by photoelectric plethysmography and heart rate by electrocardiograph. The system is intended for use of patients in medical clinics, healthcare practices and in out-patient department of hospitals.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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) 2/17/09

Division of Cardiovascular Devices

510(k) Number K083735