Ostar Meditech Corp.

K112269

510(K) SUMMARY

OCT 2 0 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 on June 20, 2011.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:
   Ostar Meditech Corp.
   5F, No. 46-4, Min-Chiuan Rd., Shing-Tien Dist.,
   New Taipei City 231, Taiwan, R.O.C.

   Contact:
   Mr. Steven Chang/President & OC
   TEL No : +886-2-2918-2390
   FAX No.: +886-2-2918-2683

2. Name of the Device & Classification:
   Ostar USB Blood Pressure Monitor / Models P200, and Mini-M100.

Regulation Number	: 870.1130
Medical Specialty	: Neurology
Product Code	: DXN
Device Class	: II

3. Information of the 510(k) Cleared Device (Predicate Device):
   - HOSMAN model HM500 (K103046) for P200 upper arm model
   - HOSMAN model HM100(K103046) for M100 wrist model

4. Device Description:

   Basically the measuring system were composite of blood pressure measuring circuit via Oscillometric method, pressure sensor, measuring cuff at arm, pneumatic pump, inflation and deflation system, housing, display LCD, and measuring software...and so on.

   OSTAR USB Blood Pressure Monitor Upper Arm Type : P200 and Wrist Type : M100 use the Oscillometric method to measure blood pressure. The Oscillometric method is adopted clinically to measure the blood pressure recently. It is not needed to ise the stethoscope, as in the traditional measuring method, to monitor the Korothkov sound when deciding the systolic and diastolic pressure. The Oscillometric method senses the vibrating signal via the closed air pipe system and utilizes the microcomputer to automatically sense the characteristics of the pulse signal. Through simple calculation, the reading can reflect the accurate real blood pressure, and the systolic pressure is defined as the pressure when the cuff pressure oscillating amplitude begins to increase and the diastolic pressure as the pressure when the cuff pressure oscillating stop decreasing. In addition, the heart beat rate will be also measured and displayed on LCD as part of measurement result.

   For P200 Upper Arm Type, all the measuring circuit, measuring devices, measuring and display software are all mounted on the device housing. It can be operated individually or be operated by the PC installed with measurement software through

USB connection port to control and transfer the measuring records, and then stored the records in device.

For M100 Wrist Type, all the measuring circuit, measuring devices, software are all mounted on the device housing except for the measurement control keys and display. It can be operated only by the PC installed with measurement software through USB connection port to control and transfer the measuring records, and then stored the records in device.

5. Intended Use:

OSTAR USB Blood Pressure Monitor Upper Arm Type : P200 and Wrist Type :M100, are noninvasive blood pressure measurement systems intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist or upper arm.

The cuff circumference is limited to be 5.5'~7.8'(14 cm ~20 cm) for wrist type, and 9'~13'(24cm ~32cm) for Upper Arm Type.

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ANSI/AAMI, SP 10-2002/A1:2003, as well as EN 60601-1, and EN 60601-1-2 requirement.

For the cuff of blood pressure monitor, the skin contact materials are in compliance with ISO 10993-1, ISO-10993-5, and ISO 10993-10.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

7. Conclusions

The Ostar USB Blood Pressure Monitor / Models P200 for blood pressure measurement at upper arm, and M100 for blood pressure measurement at wrist have the same intended use and technological characteristics as the cleared device of HOSMAN model HM500 (K103046) for P200 upper arm model and HOSMAN model HM100(K103046) for M100 wrist model. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

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

OCT 2 0 2011

Ostar Meditech Corp.
c/o Mr. Steven Chang
Official Correspondent
5F, No. 46-4, Min-Chiuan Road
Shing-Tien Dist.
New Taipei City
CHINA (TAIWAN) 231

Re: K112269
Trade/Device Name: Ostar USB Blood Pressure Monitor, Models P200 and M100 Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: June 20, 2011
Received: August 8, 2011

Dear Mr. Steven Chang:

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 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,

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

Enclosure

Indications For Use

510(k) Number (if known): K112269

Device Name: Ostar USB Blood Pressure Monitor / Models P200, and M100.

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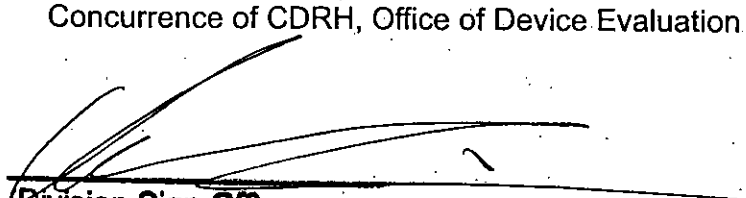
Prescription Use _____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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(Division Sign-Off)
Division of Cardiovascular Devices

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