K090027
p1/2

Zen Strong Medical Technology Co., Ltd.

FEB - 2 2009

510(K) SUMMARY

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.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:
   Zen Strong Medical Technology Co., Ltd.
   6F No. 88, Ning Jin St., Keelung, Taiwan, R.O.C.
   Contact: Cheng Roei-Sheng
   Date of Summary Preparation: December 31, 2008

2. Name of the Device:
   Blood Pressure Monitor, models ZSBP-003/004/005/006/007/008 for wrist type and ZSBP-102/103/104/105/106/107 for upper arm type.

3. Classification information:

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

4. Device Description:

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

   The main operation for the blood pressure measurement is carried out in such a way that the measuring cuff at wrist or upper arm is inflated to the estimated pressure level, then deflated to zero automatically. During the inflation and deflation, the pressure change with respective of time were recorded as the data base of measurement. Then the following measuring results will be calculated against the measurement data base:
   - Blood pressure information including systolic and diastolic pressure (calculated via Oscillometric method)
   - Heart beat rate.

5. Intended Use:

   ZSBP-003/004/005/006/007/008 blood pressure monitors measure automatically human being systolic, diastolic blood pressure and heart beat rate from wrist by using the oscillometric method for all ages of person.
   ZSBP-102/103/104/105/106/107 blood pressure monitors measure automatically human being systolic, diastolic blood pressure and heart beat rate from upper arm by using the Oscillometric method for all ages of person.
   All measurement values can be read out and keep memory on the LCD panel for home care use.

6. Comparison to the 510(k) Cleared Device (Predicate Device):
   ZSBP-001, ZSBP-002, and ZSBP-101 (K070473).

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
   Compliance to applicable voluntary standards includes ANSI/AAMI, SP 10, as well as EN 60601-1, and EN 60601-1-2 requirement.

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

8. Conclusions

   The Zen Strong model ZSBP-003/004/005/006/007/008blood pressure monitors (measurement at wrist) have the same intended use and technical characteristics as the cleared model ZSBP-001 and ZSBP-002 (K070473), and ZSBP-102/103/104/105/106/107 blood pressure monitors (measured at upper arm) have the same intended use and technical characteristics as the cleared model ZSBP-101 (K070473).

   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 devices.

   In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device, and the new models as mentioned on this submission are considered substantial equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2009

Zen Strong Medical Technology Co., Ltd.
c/o Ms. Cheng Roie-Sheng
6F, No. 88, Ning Jin Street,
Nuannuan District, Keelung City,
Taiwan, R.O.C.

Re: K090027
Trade/Device Name: Blood Pressure Monitor, Models ZSBP-003/004/005/006/007/008 for wrist type and ZSBP-102/103/104/105/106/107 for upper arm type
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: December 31, 2008
Received: January 5, 2009

Dear Ms. Roie-Sheng:

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

K090027

Indications For Use

510(k) Number (if known): K090027

Device Name: Blood Pressure Monitor, models ZSBP-003/004/005/006/007/008 for wrist type, and ZSBP-102/103/104/105/106/107 for upper arm type.

Indications For Use:

ZSBP-003/004/005/006/007/008 blood pressure monitor measures automatically human being systolic, diastolic blood pressure and heart beat rate from wrist by using the Oscillometric method for the patient of the age over 18 years old.

ZSBP-102/103/104/105/106/107 blood pressure monitor measures automatically human being systolic, diastolic blood pressure and heart beat rate from upper arm by using the Oscillometric method for the patient of the age over 18 years old.

All measurement values can be read out and keep memory on the LCD panel for home care use.

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)

Donna R. Vorhees

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090027