DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 31, 2016

Zhejiang Haisheng Medical Device Co., Ltd.
Jonathan Hu, Technical Manager
Medwheat (shanghai) Medical Technology Co.,ltd..
Yangpu Distrist Liaoyuan East Road Shuangyang
First Suite No.33 Room 303
Shanghai, 200093 CN

Re: K152472
Trade/Device Name: Disposable Blood Pressure Transducer
Regulation Number: 21 CFR 870.2850
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II
Product Code: DRS
Dated: September 27, 2016
Received: October 7, 2016

Dear Jonathan Hu:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

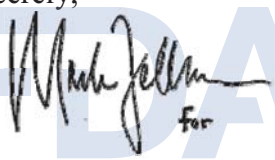
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,



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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152472

Device Name
Disposable Blood Pressure Transducer

Indications for Use *(Describe)*
The Disposable Blood Pressure Transducer (DBPT) is intended for direct measurement and monitoring of fluid pressure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Date Prepared: Aug 25th, 2015

510(k) Summary

[As required by 21 CFR 807.92]

1. Submitter's Information

Name of Sponsor:	ZHEJIANG HAISHENG MEDICAL DEVICE CO., LTD.
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2. Correspondent's Information

Company Name:	Medwheat Shanghai
Correspondent Name:	Jonathan Hu
Telephone No.:	0086-021-65181421
Email Address:	Jonathan.hu@medwheat.com

3. Trade Name, Common Name, Classification

Trade Name:	Disposable Blood Pressure Transducer
Common Name:	Disposable Pressure Transducer
Mode Name:	DBPT series
Regulation Classification	870.2850
Product Code:	DRS
Classification Panel:	Cardiovascular
Device Class:	II

4. Identification of Predicate Device(s)

The identified predicates within this submission are as follows:

Transpac® Disposable Straight Pressure Transducer (DSPT) as cleared in K061573.

5. Description of the Device

The Disposable Blood Pressure Transducer (DBPT) is an extravascular pressure transducer that interfaces between a catheter and pressure monitor by converting changes in pressure into electrical currents that can be input into a compatible pressure monitor. The major components of the DBPT include the DBPT module that houses a ceramic, a luer connector with locking collar that can connect to an intravascular catheter, a transducer cable that can connect to a compatible pressure monitor and a stopcock for altering direction of fluid flow. The DBPT is provided sterile and for single use.

6. Indication for Use

The Disposable Blood Pressure Transducer (DBPT) is intended for direct measurement and monitoring of fluid pressure.

7. Technological Characteristics

As the reason that the working situation and environment of Disposable Blood Pressure Transducer (DBPT) is the same as that of the similar Transpac® Disposable Straight Pressure Transducer (DSPT), the technological characteristics of this product series are designed to make same as that of the equivalence product, including product structure such as stopcock, flush device, etc., and such as the application of materials over different parts of the product series are also be designed to be equal respectively. It applies EO sterilization method, which is also same as that of SE product.

8. Discussion of Non-clinical Testing

The proposed device, Disposable Blood Pressure Transducer (DBPT) has been conducted related non-clinical tests to identify the substantial equivalence from the predicate device. The tests include the concerning of biocompatibility, product performance and safety tests, which contains the standards including ASTM F756-13, ISO 10993-5:2009, ISO 10993-10 3Ed:2010, ISO 10993-11:2006, IEC 60601-2-34 3Ed:2011, and ANSI/AAMI BP22:1994 (R) 2011.

9. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, it is concluded, basing on performance testing, indication for use, and technology, the subject device is substantially equivalent to the predicate device K061573.