K091408
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Section III 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date of Submission:	May 11, 2009
Sponsor:	Shenzhen ANT Hi-Tech Industrial Co., Ltd Building 11, Lishan Industrial Park, Xinghai Ave Nanshan District, Shenzhen, Guangdong, 518052, China
Correspondent:	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Suite 8D, No.19, Lane 999,Zhongshan Road (S-2),Shanghai, 200030, China
Proposed Device	**Disposable Pressure Transducer**
Classification:	Class II, DRS, 870.2850
Predicate Device:	Transpac® Disposable Straight Pressure Transducer (DSPT) as cleared in K061573
Intended Use:	The disposable pressure transducer (DPT) is intended for direct measurement and monitoring of invasive blood pressure, intrauterine pressure, urine-dynamic pressure, compartmental (intramuscular) pressure and intracranial pressure.
Device Description:	The proposed device, disposable pressure transducer (DPT), is an extravascular pressure transducer interfaces between an intravascular catheter and monitor by converting changes in pressure into electrical currents that can be impute into a compatible patient monitor. It is for single use; DPT mainly consists of a transducer which converting the pressure changes to electrical currents, a luer connector which can be connected to an intravascular catheter, a transducer cable that can connect to a compatible patient monitor and a stopcock for altering direction fluid flow.
Testing Conclusion:	Performance testing was conducted to validate and verify that the proposed device, Disposable Pressure Transducer (DPT) met all design specifications and was substantially equivalent to the predicate device.
SE Conclusion:	The proposed device, Disposable Pressure Transducer (DPT) is claimed to be substantially equivalent to the predicate device, Transpac® Disposable Straight Pressure Transducer (DSPT) as cleared in K061573.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 1 8 2009

Shenzhen Ant Hi-Tech Industrial Co., Ltd.
c/o Mr. Lee Fu
Shanghai Mid-Link Business Consulting Co., Ltd.
Suite 8D, No. 19 Lane 999
Zhongshan Road (S-2)
Shanghai, 200030
CHINA

Re: K091408
Trade/Device Name: Disposable Pressure Transducer
Regulatory Number: 21 CFR 870.2550
Regulation Name: Extravascular Blood Pressure Transducer
Regulatory Class: Class II (two)
Product Code: DRS
Dated: August 3, 2009
Received: August 5, 2009

Dear Mr. Fu:

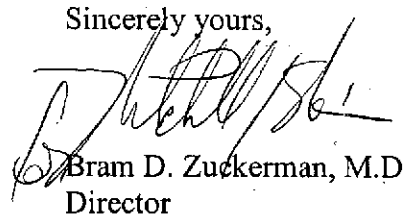
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

K091408

Section II Indication for Use

510(k) Number:

Device Name: Disposable Pressure Transducer

Indications for Use:

The disposable pressure transducer (DPT) is intended for direct measurement and monitoring of invasive blood pressure, intrauterine pressure, urine-dynamic pressure, compartmental (intramuscular) pressure and intracranial pressure.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091408