

SUNWEI TECH Co. Ltd.
Pre-market Notification for VASORING* VRC

OCT - 5 2006

**VASORING* VRC Vascular Ring Connector
of 6mm and Larger Diameter
510(k) Summary of Safety and Effectiveness**

1. Submitter's Name:

SUNWEI TECH Co. Ltd.
3rd Floor, 42, Sec. 2, Jhongcheng Road, Shih Lin District
Taipei 111, TAIWAN
Contact: Cassy Mao, Director of Operations.

2. Name of Device

Common/Usual Name: Vascular Ring Connector
Proprietary Name: VASORING* VRC Vascular Ring Connector
Classification Name: Prostheses, Vascular Graft, of 6mm and Greater Diameter

3. Predicate Device

<u>Trade Name</u>	<u>510(k) Number</u>	<u>Decision Date</u>
Meadox Intra-Aortic Graft	K881283	05/26/1988
Titanium GREENFIELD Vena Cava Filter	K874096	11/04/1988
St. Jude Symmetry Aortic Clip	K003446	05/21/2001

4. Device Description

The vascular ring connector is made of biocompatible titanium alloy. Placed in the vascular prosthesis to form a Graft-Connector Unit, it can be used as an intraluminal graft. The braided ligature tape (Ethicon[®] Nylon Tape) is for tying the ring connector from outside of the blood vessel to provide sutureless anastomosis that is time-saving. There are two grooves on the outer surface of the connector: the narrow groove is for suture fixation between the connector and the vascular prosthesis; and the wider groove is for ligature fixation between the connector and the blood vessel. The titanium alloy allows the ring connector to be of thin-wall design which gives larger inner diameter while maintaining adequate mechanical strength at the anastomotic sites.

*Trademark

5. Indication for Use

The VASORING* VRC Vascular Ring Connector is indicated for use as a connector for attaching a vascular graft to native tissue where conditions preclude a conventional end-to-end sutured anastomosis.

6. Technological Characteristics

The VASORING* VRC Vascular Ring Connector is identical to the Meadox Intra-Aortic Graft polyester connector with respect to intended use. The titanium alloy ring is of cylindrical shape with an outside diameter ranging from 6mm to 30mm for use with various sizes of aorta to achieve proper anastomoses.

7. Performance Summary

Bench testing was performed to ensure that VASORING* VRC will meet all functional and performance requirements for its intended use. The titanium alloy connector was also tested for material biocompatibility per ISO 10993 guidelines. Two pre-clinical animal studies were performed to investigate the thrombogenicity phenomena; a 4-hours study to assess immediate impact of using the VRC for anastomoses, and the other was a 20-week observation of the test animals. All bench tests, biocompatibility tests, and thrombogenicity studies demonstrated satisfactory performance of the VASORING* VRC connectors.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2006

SUNWEI TECH Co. Ltd
c/o Joseph J. Chang, PhD, P.E.
Consultant
Innomedtech LLC
7128 Staffordshire Street
Houston, TX 77030

Re: K061626
Vasoring VRC Vascular Ring Connector
Regulation Number: 21 CFR 870.3460
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II (Two)
Product Code: DSY
Dated: September 21, 2006
Received: September 22, 2006

Dear Dr. 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 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.

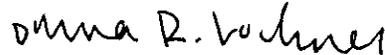
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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

Indications for Use

510(k) Number (if known): K061626

Device Name: VASORING VRC Vascular Ring Connector

Indications For Use:

The VASORING VRC Vascular Ring Connector is indicated for use as a connector for attaching a vascular graft to native tissue where conditions preclude a conventional end-to-end sutured anastomosis.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Anna P. Beckner
(Division Supervisor)
Division of Cardiovascular Devices

510(k) Number: K061626