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510 (k) summary

FEB - 8 2012

5. 1 Submitter

Synexmed (Shenzhen) company limited
B-11/F, ZTY Building, Taohua Road, Futian Free Trade Zone
Shenzhen, 518038, China
Tel: (86 755) 8358 0375
Establishment Registration Number: 3008388400

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5.2 Device

Trade name:	IM Band
Classification Name:	Clamp, vascular
Classification:	Class II
Common Name:	Artery Compression Band
Regulation Number:	870.4450

5.3 Predicate Device

The predicate devices used to determine substantial equivalence for the TR Band by the Terumo Medical Corporation (#K070423)

5.4 Device Description

The IM Band ™ Adjustable Arterial Compression Band is intended to be used to oppress the vascular puncture in order to stop the bleeding by the inflation of a balloon. Transparent balloon material allows clear monitoring of the hemostasis time. Oppressing inside the balloon can be adapt to the skin surface for better contact. Bleeding can be stopped by simply adjusting the band or turncap according to doctor's instruction. Soft and adjustable wrist band enhances patient comfort.

5.5 Intended Use

The IM Band ™ Adjustable Arterial Compression Band is a compression device to assist hemostasis of the radial artery after a transradial procedure..

5.6 Comparison of Characteristics

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics, and sterilization are identical or substantially equivalent to the currently marketed predicate devices.

5.7 Performance Data

The results of the performance testing demonstrated the safety and effectiveness of the IM Band ™ Adjustable Arterial Compression Band

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

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Synexmed (Shenzhen Company, Ltd.
% Mr. Yongwei Chien, CEO
B-11/F, ZTY Building
Taohua Road, Futian Free Trade Zone
Shenzhen, 518038, China

Re: K113600
Trade/Device Name: IM Band™ Adjustable Arterial Compression Band
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC
Dated: November 30, 2011
Received: December 05, 2011

Dear Mr. Chien:

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 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113600

Device Name: IM Band ™

Indications For Use:

The IM Band ™ is a compression device to assist hemostasis of the radial artery after a transradial procedure.

Prescription Use __X_____ 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mkn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K 113600