K132293 JUL 31 2014

VIII. 510(k) Summary

I. General Information

A. Applicant's Name and Address:

Marine Polymer Technologies, Inc. (MPT)
107 Water Street
Danvers, MA 01923

B. Contact Person:

Sergio Finkielsztein
President
Tel: 781-270-3200 x13
Fax: 781-270-1133

C. Manufacturer's Name and Address:

Marine Polymer Technologies
461 Boston Road, Suite B5
Topsfield, MA 01983
Tel: 978-887-0341
Fax: 978-887-0329

D. Establishment Registration Number:

FDA Registration Number: 1225598 (Marine Polymer Technologies, Inc.)

E. Device Trade or Proprietary Names	Syvek Radial Band
F. Classification Number/ Name:	21 CFR § 870.4450 Vascular Clamp
G. Regulatory Class:	Class II (two)
H. Product Code:	DXC

II. Indications for Use

A. Intended Use:
Syvek Radial™ Band is a compression device to assist hemostasis of the radial artery after a transradial procedure.

III. Device Description

Syvek Radial™ Band is a sterile, single use, disposable device. The Syvek Radial™ Band is a radial artery compression device consisting of a clear medical grade polyurethane compression bladder, which is connected to both the pump and the release valves.

IV. Substantial Equivalence-Predicate Devices:

Datascope Corp.; Air-Band Radial Compression Device (K122405)

V. Design Characteristics:
The Syvek Radial™ Band has the same intended use and configuration (wristband) as the predicate device, AIR- BAND (K122405). The materials used are equivalent and the product design is similar to that of the predicate device. Syvek Radial™ Band is manually operated (inflated/deflated) like the predicate device.

VI. Performance Data: To demonstrate substantial performance equivalence to the predicate devices, biocompatibility and bench top testing was performed. Performance Testing included:

- Biocompatibility Testing
- Pressure Equivalence to Predicate (AIR-BAND)

VII. Product Sterilization:
Each Syvek Radial™ Band is individually packaged in a two ply coated paper/polyester heat sealable pouch, which is a packaging commonly used in the medical device industry in the United States. Terminal sterilization is accomplished on the final packaged products by ionizing radiation.

VIII. Summary:

Marine Polymer Technologies has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that Syvek Radial™ Band is substantially equivalent to a currently marketed predicate device.

Bench top testing was performed to demonstrate substantial performance equivalence to the predicate device. Performance Testing included:

- Biocompatibility – Cytotoxicity, Sensitization, and Irritation/Intracutaneous Reactivity testing performed per ISO 10993 Biological Evaluation of Medical Devices. The conclusion drawn from the results of biocompatibility testing indicated the test articles met all test requirements.

- Pressure Equivalence to Predicate (AIR-BAND) – Pressure equivalency testing included both peak and hold pressure for extended periods of time. The Syvek Radial™ Band and the predicate device demonstrated similar performance in this testing.

The conclusions drawn from nonclinical testing demonstrate that the Syvek Radial™ Band is as safe, effective and performs as well as the legally marketed predicate device, AIR-BAND.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 31, 2014

Marine Polymer Technologies
Sergio Finkielsztein
President
107 Water Street
Danvers, Massachusetts 01923

Re: K132293
Trade/Device Name: Syvek radial band
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: June 27, 2014
Received: June 30, 2014

Dear Mr. Finkielsztein,

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 yours,

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

Enclosure

Indications for Use Statement

510(k) Number K132293

Device Name: Syvek Radial™ Band

Indications for use:

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

Prescription Use __X___ (Per 21 C.F.R. 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)