510(k) Summary K122405

Datascope Corp.
Premarket Notification Traditional 510(k)
AIR-BAND™ Radial Compression Device

Date: August 6, 2012

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Submitter: Datascope Corp.
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Fairfield, NJ 07004

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Device Trade name: AIR-BAND™ Radial Compression Device

Common/Usual Name: Compression Device

Classification Name: 21 CFR 870.4450 Vascular Clamp

Predicate Devices: K070423 TR Band™
K062569 Safeguard® 24cm Pressure Assisted Dressing

Device Description: AIR-BAND™ is a sterile, single use, 6-month shelf life, disposable device. It has a clear medical grade polyurethane window and bulb that facilitates visualization of the puncture site, a clear medical grade PVC flexible tube, and a pressure sensitive, self-adhesive peel backing. A luer valve on the end of the fill tube enables a luer lock syringe to be connected to inflate and deflate the bulb with air to provide compression of the transradial puncture site.

Intended Use: The AIR-BAND™ Radial is a compression device to assist hemostasis of the radial artery after a transradial procedure.

Design Characteristics:
The AIR-BAND™ has the same intended use and configuration (wristband) as the predicate device, TR Band™ (K070423). The materials used are equivalent and the product design is similar to that of the predicate device Safeguard® 24cm Pressure Assisted Dressing (K062569). The AIR-BAND™ is manually operated (inflated/deflated) like both predicate devices.

Performance Data: Bench top testing was used to demonstrate substantial performance equivalence to the predicate devices. Performance Testing included:

- Biocompatibility Testing
- Pressure Equivalence to Predicate (TR Band)
- Packaging Performance
- Product Stability (Shelf Life)
- Product Sterilization

Summary: The AIR-BAND™ submitted in this 510(k) has essentially the same intended use, design/ technological and performance characteristics as the predicate devices. The results of all testing demonstrate that the AIR-BAND™ Radial Compression Device is as safe, as effective, and performs as well as the predicate devices.

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

NOV 9 2012

Datascope Corp., Cardiac Assist Division
% Ms. Carla Cerqueira
15 Law Dr.
Fairfield, NJ 07004-0011

Re: K122405
Trade/Device Name: Air-band radial compression device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: October 5, 2012
Received: October 9, 2012

Dear Ms. Cerqueira:

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 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,

Matthew G. Hillebrenner

Digitally signed by Matthew G. Hillebrenner
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300213272, cn=Matthew G. Hillebrenner
Date: 2012.11.08 16:15:12 -05'00'

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): K122405

Device Name: AIR-BAND™ Radial Compression Device

Indications For Use: The AIR-BAND™ Radial 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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122405