



Food and Drug Administration
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August 29, 2017

Tricol Biomedical, Inc.
Máire Ní Beillíú
Vice President Regulatory & Quality
720 SW Washington Street, Suite 200
Portland, Oregon 97205

Re: K170958

Trade/Device Name: ChitoPulse 9in/23cm, ChitoPulse 12in/30.5cm, ChitoPulse 15in/38cm
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: July 26, 2017
Received: July 31, 2017

Dear Dr. Ní Beillíú:

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 (DICE) 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 (DICE) 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,

Nicole G. Ibrahim -S

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

510(k) Number (if known)
K170958

Device Name
HemCon® ChitoPulse™

Indications for Use (Describe)

ChitoPulse™ Radial Hemostatic Device is intended to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's radial artery, including arterial or venous line or sheath removal, hemodialysis and in patients on anticoagulation therapy.

ChitoPulse™ Hemostatic Device is intended to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's leg, including dorsalis pedis or tibial blood vessels, arterial or venous line or sheath removal and in patients on anticoagulation therapy.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1. 510(k) Summary

Tricol Biomedical Inc 510(k) Notification

I. Submitter:

Company Name: Tricol Biomedical, Inc.
Company Address: 720 SW Washington Street, Suite 200
Portland, OR 97205-3504

Contact Person: Máire E. Ní Beilliú PhD
Vice President Regulatory & Quality
Contact Phone: (971) 327.5729
Contact Fax: (503) 245.1326

Date of Preparation: 28th August 2017

II. Device

Trade Name: **HemCon® ChitoPulse™**
Common Name: Vascular Compression Device, Hemostat
Classification Name: Vascular Clamp (21 CFR 870.4450)
Product Code: DXC
Regulatory Class: Class II (Performance Standards)
Classification Panel: 870 – Cardiovascular Devices

III. Predicate Device(s):

Primary Predicate Device: Zephyr Vascular Compression Devices (K151363)

Secondary Predicate Device: Vasc Band Hemostat (K142359)

Reference Device(s): HemCon® Patch PRO (K150916)

IV. Description of the Device:

ChitoPulse™ is a mechanical compression band incorporating a hemostatic chitosan patch. The compression band and chitosan patch are positioned over the radial access site and secured in place by a strap fastener. Addition of air to the compression band balloon provides rapid bleeding control by localized compression.

The chitosan patch provides adjunct bleeding control to the balloon compression and provides a barrier against bacterial penetration by a wide range of gram positive and gram negative organisms.

Compression is applied or reduced using a syringe and luer lock valve to add or remove air volume to or from the balloon. Once hemostasis has been achieved, compression may be reduced by gradual removal of air from the balloon.

ChitoPulse™ is a single use device. Once hemostasis is achieved, the compression band is intended to be removed leaving the hemostatic chitosan patch in place. The hemostatic chitosan patch can be secured in place with a securement dressing for up to 24 hrs.

V. Indications for Use:

HemCon® ChitoPulse™ Radial Hemostatic Device

ChitoPulse™ is intended to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's radial artery, including arterial or venous line or sheath removal, hemodialysis and in patients on anticoagulation therapy

HemCon® ChitoPulse Hemostatic Device

ChitoPulse™ is intended to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's leg, including dorsalis pedis or tibial blood vessels, arterial or venous line or sheath removal and in patients on anticoagulation therapy.

ChitoPulse™ Radial Hemostatic Device has the same indications for use as the primary predicate device and same intended use as the secondary predicate device.

ChitoPulse™ Hemostatic Device has the same indications for use as the primary predicate device

Both the subject and predicate devices have substantially equivalent intended use as compression devices to promote hemostasis following a catheterization or other puncture into a blood vessel in a patients arm or leg, including: radial, brachial, dorsalis pedis or tibial blood vessels, arterial or venous line or sheath removal, hemodialysis and in patients on anticoagulation therapy.

Both the subject and predicate devices are intended to be used by trained medical professionals.

VI. Comparison of Technological Characteristics with the Predicate Devices:

Both the subject device and primary predicate device are intended to promote hemostasis following a catheterization or other puncture into a blood vessel in a patients arm or leg, including: radial, brachial, dorsalis pedis or tibial blood vessels, arterial or venous line or sheath removal, hemodialysis and in patients on anticoagulation therapy.

Both the subject device and predicate devices are composed of biocompatible PVC straps that are applied around a limb and fastened with hook and loop material.

Both the subject and predicate devices use inflatable balloons to apply compression to the limb thereby applying pressure to the underlying vasculature.

The subject and predicate devices differ in that the subject device has a chitosan patch that is intended to be left *in situ* for up to 24 hours following removal of the compression band. The chitosan patch acts as an adjunct to the mechanical compression provided by the strap and inflatable balloon.

VII. 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 testing
- Bacterial barrier testing (chitosan patch)

Sterility

Each ChitoPulse™ is individually packaged in a heat sealed foil pouch and is terminally sterilized by gamma irradiation to a sterility assurance level (SAL) of 10^{-6} .

Biocompatibility Testing

Biocompatibility testing for ChitoPulse™ has been conducted in accordance with the FDA Guidance Document "Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", June 16th 2016 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" as recognized by FDA.

Categorization of the device by nature of body contact deduces that ChitoPulse™ is a surface contacting device, device is intended for limited contact (≤ 24 hrs).

Cytotoxicity, intracutaneous irritation, dermal irritation, sensitization, and acute systemic toxicity were performed by contract testing laboratories per ISO 10993 standard protocols.

Bacterial Barrier Properties

The barrier properties of the chitosan patch have been demonstrated *in vitro* using AATCC Test Method 100-2004, Antibacterial Finishes on Textiles - Evaluation of (Technical Manual of the American Association of Textile Chemists and Colorists). The results of the test demonstrated the chitosan patch is capable of preventing bacterial penetration.

Performance Testing

Benchtop pressure equivalence testing was performed to demonstrate that ChitoPulse™ applies equivalent pressure as the predicate Vasc Band Hemostat device. The tensile strength of the ChitoPulse™ strap was also evaluated and demonstrated to be equivalent to the predicate Vasc Band Hemostat device.

Clinical Performance Data:

No clinical data was required for evaluation of this device.

Summary:

The conclusion drawn from the technological characteristics and non-clinical performance data is that the HemCon® ChitoPulse™ has been found to be substantially equivalent to the predicate devices.