



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

March 21, 2017

Biostable Science & Engineering Inc.
% Ms. Janice Hogan
Partner
Hogan Lovells US LLP
1835 Market St, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K163608

Trade/Device Name: HAART 300 Aortic Annuloplasty Device (Sizes 19, 21, 23, and 25 mm)
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: PST
Dated: December 21, 2016
Received: December 21, 2016

Dear Ms. Hogan:

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light blue, semi-transparent "FDA" watermark.

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)

K163608

Device Name

HAART 300 Aortic Annuloplasty Device

Indications for Use (Describe)

The HAART 300 Aortic Annuloplasty Device is intended to be used to correct annular dilatation and/or maintain annular geometry of the aortic valve in patients with tri-leaflet valve morphology with moderate to severe aortic insufficiency who are undergoing aortic valve repair due to symptoms or as part of a repair for an aortic root aneurysm.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY (K163608)

Submitter: BioStable Science & Engineering, Inc.
2621 Ridgepoint Dr., Suite 100
Austin, TX 78754
Contact Person: Julie Thomas
Phone: 512-970-9112

Contact: Janice M. Hogan
Hogan Lovells US LLP
1835 Market St, 29th Floor
Philadelphia, PA 19103
Phone: 267-675-4611
Facsimile: 267-675-4601

Date Prepared: December 21, 2016

Trade Name: HAART 300 Aortic Annuloplasty Device

Common Name: Annuloplasty Ring

Classification: 21 CFR 870.3800
Product Code: PST

Predicate Device: Carpentier-Edwards Physio Tricuspid Annuloplasty Ring, Model 6200
(K103520)

Device Description

The HAART 300 Aortic Annuloplasty Device is designed to return aortic annular geometry toward normal for a given leaflet size and to assist in producing adequate leaflet competence by recovering normal coaptation geometry and area. It consists of a titanium frame covered with polyester fabric that is sewn onto the frame using braided polyester suture. The device has an elliptical base geometry and three subcommissural posts positioned 120° apart around its circumference. The device is available in four sizes: 19 mm, 21 mm, 23 mm, and 25mm. The device is provided attached to a disposable holder by means of a single polyester suture. Twelve (12) polyester pledgets are provided with each HAART 300 Aortic Annuloplasty Device. Both the device and pledgets are provided sterile by gamma irradiation sterilization and are intended for single-use. The HAART 301 Instrument Set provides accessory instruments to facilitate proper sizing and implantation of the device.

Intended Use / Indications for Use

The HAART 300 Aortic Annuloplasty Device is intended to be used to correct annular dilatation and/or maintain annular geometry of the aortic valve in patients with tri-leaflet valve

morphology with moderate to severe aortic insufficiency who are undergoing aortic valve repair due to symptoms or as part of a repair for an aortic root aneurysm.

Summary of Technological Characteristics and Substantial Equivalence

The intended use, technological characteristics, and principles of operation of the HAART 300 Aortic Annuloplasty Device are substantially equivalent to legally marketed mitral and tricuspid annuloplasty devices. More specifically, the HAART 300 Aortic Annuloplasty Device is substantially equivalent to the Carpentier-Edwards Physio Tricuspid Annuloplasty Ring Model 6200 (K103520). The difference between the indications for use of the HAART 300 Device and its predicate is the anatomic position of the valve being treated. However, this has no impact on the therapeutic effect of the device, which is the same as the predicate, which is to reshape and stabilize the valve annulus during surgical reconstruction of valvular insufficiency. The technological characteristics of both devices are equivalent with the exception of the silicon sewing ring added to the Physio Annuloplasty Ring and the material of the thread used to sew the polyester cloth to the device. These differences do not raise different questions of safety and effectiveness. Both devices are provided with accessories that include instruments for sizing the device and a holder to facilitate implantation. The principles of operation including the implantation steps, are also equivalent. Differences in the characteristics do not present any new issues of safety or effectiveness. Thus, the HAART 300 Aortic Annuloplasty Device is substantially equivalent.

Performance Data

The HAART 300 Aortic Annuloplasty Device successfully completed design verification and validation testing based on the risk analysis for the device and in accordance with applicable standards and the FDA Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and FDA Staff. The following nonclinical studies were conducted:

- Biocompatibility (ISO 10993-1:2009)
- Computational structural analysis
- Tensile testing
- Suture pull-out testing
- Sterilization validation testing (ISO 11137-1:2006, ISO 11137-2:2006)
- Biological testing (ISO 10993-1:2009)
- Shelf life validation (ISO 11607:2006, ASTM F88-09, F1886-09, F192904, D4169-09)
- Fatigue testing
- Magnetic resonance compatibility testing (ASTM F2052-06e1, F2119-07, F2182-11a)
- Animal studies

Clinical Performance Data

A prospective, multi-centered, single-arm study was conducted, which enrolled a total of 65 patients. The Kaplan-Meier survival estimate was 98.4% at 6 months and 94.7% at 2 years. None of the deaths occurred during the 2-year follow-up period was device related. The percentage of patients who had greater than mild aortic insufficiency (AI) as assessed by transthoracic

echocardiography (TTE) was 23.3% at 6 months (N=56) and 25% at 2 years (N=48), as compared to 94.9% at baseline.

Conclusions

Nonclinical and clinical performance testing has demonstrated that the HAART 300 Aortic Annuloplasty Device is substantially equivalent to the predicate device, the Carpentier-Edwards Physio Tricuspid Annuloplasty Ring, Model 6200.