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

August 10, 2017

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

Re: K171431
Trade/Device Name: HAART 200 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: May 15, 2017
Received: May 15, 2017

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171431

Device Name

HAART 200 Aortic Annuloplasty Device

Indications for Use *(Describe)*

The HAART 200 Aortic Annuloplasty Device is intended to be used to correct annular dilatation and/or maintain annular geometry of the aortic valve in patients with bicuspid 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
PRAStaff@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
(K171431)

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: April 15, 2017

Trade Name: HAART 200 Aortic Annuloplasty Device

Common Name: Annuloplasty Ring

Classification: 21 CFR 870.3800
Product Code: PST

Predicate Device: HAART 300 Aortic Annuloplasty Device (K163608)

Device Description

The HAART 200 Aortic Annuloplasty Device is designed to reshape the bicuspid valve annulus to a symmetric 180° configuration, to create circular annular geometry, and to improve leaflet coaptation by bringing both cusps toward the midline of the valve. It consists of a titanium frame covered with polyester fabric that is sewn onto the frame using braided polyester suture. The device has a circular base geometry and two subcommissural posts positioned 180° apart around its circumference. The device is available in four sizes: 19, 21, 23, and 25 mm. 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 200 Aortic Annuloplasty Device. Both the device and pledgets are provided sterile by gamma irradiation sterilization and are intended for single-use. The HAART 201 Instrument Set provides accessory instruments to facilitate proper sizing and implantation of the device.

Intended Use / Indications for Use

The HAART 200 Aortic Annuloplasty Device is intended to be used to correct annular dilatation and/or maintain annular geometry of the aortic valve in patients with bicuspid 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 difference between the indications for use of the HAART 200 Aortic Annuloplasty Device and its predicate is the morphology of the aortic valve being treated. However, this change does not alter the intended therapeutic effect of the device compared to the predicate; both devices are intended to reshape and stabilize the valve annulus during surgical reconstruction of aortic valvular insufficiency. The technological characteristics of both devices are equivalent with the exception of their three-dimensional shapes. This difference does 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. Thus, the HAART 200 Aortic Annuloplasty Device is substantially equivalent to the predicate device.

Performance Data

The HAART 200 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 studies were conducted:

- Computational structural analysis
- Tensile testing
- Suture pull-out testing

Performance data provided for the HAART 300 Aortic Annuloplasty Device that support the safety and performance of the HAART 200 Aortic Annuloplasty Device include:

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

Clinical Performance Data

A prospective, multi-centered, single-arm study was conducted, which implanted a total of 16 patients with the device. Survival was 100% at 2 years. There were 34 adverse events reported during the study, among which 9 were serious, including 2 reoperations for recurrent aortic insufficiency caused by a long annular suture tail. There were no unanticipated adverse events. The percentage of patients who had greater than mild aortic insufficiency (AI) as assessed by transthoracic echocardiography (TTE) was 26.7% at 6 months (N=15) and 7.1% at 2 years (N=14), as compared to 71.5% at baseline.

Conclusions

Nonclinical and clinical performance testing demonstrated that the HAART 200 Aortic Annuloplasty Device is substantially equivalent to the predicate device, the HAART 300 Aortic Annuloplasty Device.