December 15, 2020

Keystone Heart, Ltd.
℅ Mike Winegar
Principal
Winegar Consulting, Inc.
7829 Ithaca Ln N
Maple Grove, Minnesota 55311

Re: K202226
Trade/Device Name: Keystone Heart LIM Precision Steerable TS Transseptal System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 27, 2020
Received: December 1, 2020

Dear Mr. Winegar:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202226

Device Name
Keystone Heart LIM Precision Steerable TS Transseptal System

Indications for Use *(Describe)*
The LIM Precision Steerable TS Transseptal System is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

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.

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510(k) SUMMARY

Applicant	Keystone Heart, Ltd. 15 Halamish St., PO 3170 Caesarea, Israel 3088900
Contact Person	Mike Winegar Principal Winegar Consulting, Inc. 763-639-0700 mwinegar@comcast.net
Summary Date	August 6, 2020
Proprietary Name	Keystone Heart LIM Precision Steerable TS Transseptal System
Classification	Class II
Classification Name	Introducer, Catheter
Regulation Number	21 CFR 870.1340
Product Code	DYB
Predicate Device	The Keystone Heart LIM Precision Steerable TS Transseptal System is substantially equivalent to the currently marketed BioCardia 8.5F Avance™ Steerable Introducer (K190941)
Reference Device	Agilis NxT™ Steerable Introducer (K110450)

Device Description:
The Keystone Heart LIM Precision Steerable TS Transseptal System is a sterile, single use, tri-directional introducer. The system consists of a sheath and a dilator.

The sheath has a handle assembly with a rotating knob and steering lever that deflects the distal end of the sheath. The dilator can be inserted and advanced or retracted through the inner lumen of the sheath. Hemostasis is maintained along the dilator lumen via a hemostatic valve. The dilator lumen is flushable. Once the dilator is generally in the proper position relative to the sheath, an actuator is tightened to secure the dilator to the handle. A knob is then turned to slowly advance the dilator.

Intended Use:
The Keystone Heart Transseptal System is intended to provide a dilator and sheath through which other medical devices can be delivered to targeted locations within the cardiac anatomy. The Keystone Heart Transseptal System is intended to be introduced into the body through the venous system. The distal end of the sheath may be advanced across the interatrial septum of the heart into the left atrium. The Keystone Heart Transseptal System is intended to be delivered to the targeted location using echocardiographic and/or radiographic/fluoroscopic image guidance.

Indications for Use:
The LIM Precision Steerable TS Transseptal System is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum

Summary of Technical Characteristics as Compared to the Predicate Device:
The proposed device is substantially equivalent to the design and materials in the predicate device. The Keystone Heart Transseptal System has the same intended use and fundamental scientific technology as the predicate device. All technological characteristics of the Keystone Heart Transseptal System are substantially equivalent to the predicate device, including packaging, biocompatibility, sterilization, and labeling. Where dimensional differences exist between the subject device and the predicate device, performance testing demonstrates that these differences do not adversely affect safety and effectiveness. The introducer acts as a functioning guide/platform for introduction of other diagnostic and therapeutic devices.

The Keystone Heart Transseptal System is substantially equivalent to currently marketed devices intended for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum, specifically the BioCardia 8.5F Avance® Steerable Introducer, K190941. Keystone Heart is utilizing a reference device, the St. Jude Medical Agilis NxT™ Steerable Introducer, K110450. This reference device has the same basic design and indications as both the predicate and subject device, but also has a guidewire supplied with the device. The predicate and subject devices are not supplied with a guidewire.

Summary of Technical Characteristics as Compared to Predicate

	Predicate Device BioCardia 8.5 F Avance Steerable	Reference Device St. Jude Medical Agilis NxT™ Steerable	Subject Device Keystone Heart Transseptal System
Regulation No.	**870.1340**	**870.1340**	**870.1340**
Product Code	**DYB**	**DYB**	**DYB**
510(k) No.	**K190941**	**K110450**	**TBD**
Indications for Use	The BioCardia 8.5 F Avance Steerable Introducer is intended for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum	The 82cm Agilis NxT™ Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart via the venous anatomy, including the left side of the heart through the interatrial septum	The Keystone Heart Transseptal System is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum
Internal Diameter	8.5 F		8.5 F
Effective Length (cm)	71		71
Total Length	88.5		84.5
Curve Diameter (mm)	20, 30, 50		Dynamic
Guidewire	Not Included	Included	Not Included
Maximum Guidewire	0.038”		0.032”
Maximum Deflection	180° Bi-directional		180° Primary +/-45° Secondary
Shaft Deflection	Two pull wires wrapped helically around catheter shaft		3 pull wires. One for primary deflection and two for secondary lateral.
Deflection Mechanism	Levers on handle		Primary-Rotating knob on handle Secondary-Lever
Radiopaque Tip	Yes		Yes
Hemostasis	Rotating valve		Static valve
Sterilization	Ethylene Oxide		Ethylene Oxide

Performance Data:
The technical characteristics between the subject device and the predicate device have been evaluated through design, material and dimensional comparison, bench, and biocompatibility tests to provide evidence of substantial equivalence. The Keystone Heart Transseptal System is substantially equivalent to the predicate devices based on comparison of the devices functionality, compatibility, technological characteristics and indications for use.

In vitro bench testing was performed on the Keystone Heart Transseptal System to assure reliable design and performance. The non-clinical tests performed include Visual Inspection and Dimensional Analysis, Primary and Secondary Deflection, Insertion and Removal, Dilator Lock and Buckle, Leak and Flush, Femoral and Septal Insertion, Torque Test, and Fluoroscopy and Ultrasound Visualization.

Biocompatibility testing consisted of Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity, Pyrogenicity, ASTM Hemolysis (Direct and Indirect), SC5b-9 Complement Activation, Partial Thromboplastin Time, and *In Vivo* Thrombogenicity.

No animal or human testing was conducted on the Keystone Heart Transseptal System.

Conclusion:
Keystone Heart believes the proposed Keystone Heart Transseptal System is substantially equivalent to the legally marketed predicate device. The indications for use, methods of operation, design and materials used are either identical or substantially equivalent to the existing legally marketed predicate product.