May 17, 2019

CardioGard Medical Ltd
% Sheila Hemeon-Heyer
President and Founder
Heyer Regulatory Solutions, LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K182302
Trade/Device Name: CardioGard Emboli Protection Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: NCP
Dated: April 19, 2019
Received: April 22, 2019

Dear Sheila Hemeon-Heyer:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Nicole Ibrahim
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)*
K182302

Device Name

CardioGard Emboli Protection Cannula

Indications for Use *(Describe)*

The CardioGard Emboli Protection Cannula combines the function of a standard arterial cannula with an added suction mechanism to capture debris that may result from cardiac surgery.

The CardioGard Emboli Protection Cannula is intended for perfusion of the ascending aorta during short term (<6 hours) cardiopulmonary bypass (CPB) procedures. The CardioGard suction lumen is intended for the removal of particulate emboli during surgical procedures that require CPB.

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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:

Heyer Regulatory Solutions LLC
P.O. Box 2151
Amherst, MA 01004-2151
Contact: Sheila Hemeon-Heyer
Sheila@heyer-regulatory.com

B. Manufacturer Contact:

CardioGard Medical Ltd.
6 Yoni Netanyahu Street
6037604 Or-Yehuda, Israel
Contact: Doug Post
CEO, CardioGard, Inc.
Tel: (707) 481-0602
doug@cardiogard.com

C. Date Prepared: May 15, 2019

D. Device Name and Classification Information:

Trade Name:	CardioGard Emboli Protection Cannula
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Product Code, CFR:	NCP, 21 CFR 870.4210
Review Panel:	Cardiovascular Devices
Class:	II

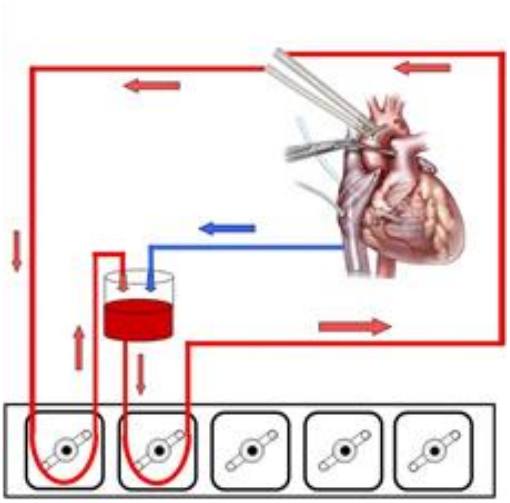
E. Predicate Device: K141465 CardioGard Emboli Protection Cannula

F. Device Description:

The CardioGard Emboli Protection Cannula (CardioGard Cannula) is a sterile, single-use, disposable double lumen arterial cannula. The CardioGard Cannula features a tip configuration that diffuses oxygenated blood from the heart-lung machine into the ascending aorta through the Cannula Outlet, while also aspirating blood and embolic matter through the Suction Lumen Inlet. The flow rates through the two cannula lumens are carefully controlled so that emboli are suctioned back to the heart-lung machine for filtration while still enabling sufficient blood flow to the patient.

During routine use, maximum flow rates should be ≤ 5.5 L/min (main) and ≤ 0.5 L/min (suction), for a net flow of ≤ 5 L/min. During periods of increased particle release, e.g., clamping and declamping, flows can be increased up to 6 L/min (main) and 1.0 L/min (suction) for not more than 10 minutes each hour.

CardioGard Features



CardioGard Inserted in the Heart-Lung Circuit

G. Indication for Use:

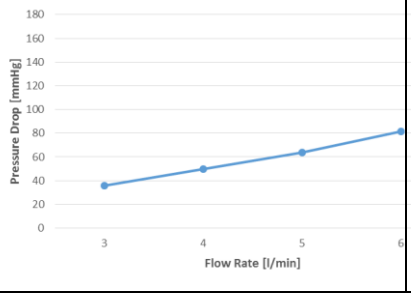
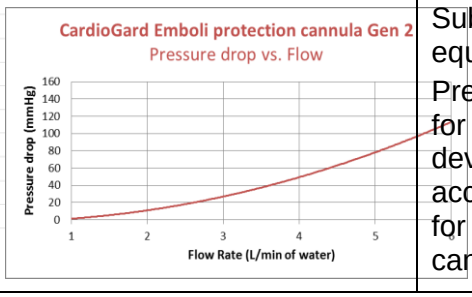
The CardioGard Emboli Protection Cannula combines the function of a standard arterial cannula with an added suction mechanism to capture debris that may result from cardiac surgery.

The CardioGard Emboli Protection Cannula is intended for perfusion of the ascending aorta during short term (<6 hours) cardiopulmonary bypass (CPB) procedures. The CardioGard suction lumen is intended for the removal of particulate emboli during surgical procedures that require CPB.

H. Technical Comparison with Predicate Device

The modified CardioGard Cannula has the same intended use and same indications for use as the original CardioGard Cannula cleared under K141465. The device dimensions, tip design, and suction tube orientation have been modified to reduce device bulk and improve ease of use without changing the device safety or effectiveness profile. The table below provides a side-by-side comparison of the modified to legally marketed CardioGard Cannula.

	Cleared Device CardioGard Emboli Protection Cannula – K141465	Modified Device CardioGard Emboli Protection Cannula	Same or Discussion of Differences
Intended use	The CardioGard Emboli Protection Cannula combines the function of a standard arterial cannula with an added suction mechanism to capture debris that may result from cardiac surgery. The CardioGard Emboli Protection Cannula is intended for perfusion of the ascending aorta during short term (≤ 6 hours) cardiopulmonary bypass (CPB) procedures. The CardioGard suction lumen is intended for the removal of particulate emboli during surgical procedures that require CPB.	The CardioGard Emboli Protection Cannula combines the function of a standard arterial cannula with an added suction mechanism to capture debris that may result from cardiac surgery. The CardioGard Emboli Protection Cannula is intended for perfusion of the ascending aorta during short term (≤ 6 hours) cardiopulmonary bypass (CPB) procedures. The CardioGard suction lumen is intended for the removal of particulate emboli during surgical procedures that require CPB.	Same
Use duration	For the length of the CPB surgery (≤ 6 hours)	For the length of the CPB surgery (≤ 6 hours)	Same
Cannula Design	Two lumen, curved tip with two ports. One port is for aortic perfusion of oxygenated blood to the patient. The second port is for suction of embolic particles from the aortic arch.	Two lumen, curved tip with two ports. One port is for aortic perfusion of oxygenated blood to the patient. The second port is for suction of embolic particles from the aortic arch. Suction tube angles 90° around the tip.	Substantially equivalent. Placement of suction tube angled to reduce cannula profile
Tip Angle	30° to 60°	30° to 60°	Substantially equivalent.
Tip Shape	Angled	Angled and tapered with dispersion side holes	Tip tapered for ease of insertion
Flange	Flange for suturing tip in place	Redesigned flange to facilitate suturing in place	Dispersion side holes added to reduce back pressure Redesigned flange for ease of use

	Cleared Device CardioGard Emboli Protection Cannula – K141465	Modified Device CardioGard Emboli Protection Cannula	Same or Discussion of Differences
Dimensions	Tip Size: 24Fr Main tube diameter: 3/8" Suction tube diameter: 1/4" Length: 30cm (both tubes same length)	Tip Size: Starts at 24Fr, ends at 22 Fr (at the insertion tip) Main tube: diameter: 5/16'' tapered to 3/8'' length: 19 – 21 cm Suction tube: diameter: 3/16'' tapered to 1/4'' length: 18 – 19 cm	Substantially equivalent. Slight modifications made to reduce cannula bulk and improve ease of use
Connectors	Connector to heart-lung machine tubing on main tube	Connectors on both main and suction tubes	Substantially equivalent. Added connector to suction tube for user convenience
Caps	Vented cap on main tube	Caps on both tubes: red for main tube and yellow for suction tube	Substantially equivalent. Color coded caps on both tubes for user convenience
Main (perfusion) flow rate range	1 – 6 L/min	1 – 6 L/min	Same
Suction flow rate range	0 – 1.5 L/min	0 – 1.0 L/min	Substantially equivalent. Max suction flow rate reduced to provide for 5 L net forward flow.
Pressure Drop			Substantially equivalent. Pressure drop for both devices within accepted range for aortic cannulas

	Cleared Device CardioGard Emboli Protection Cannula – K141465	Modified Device CardioGard Emboli Protection Cannula	Same or Discussion of Differences
Biological Safety	Tip: PVC Tubes: PVC (Plastisol) with stainless steel inner spring Connector: ABS plastic Cap: Polyethylene	Tip: Polycarbonate Tubes: PVC (Plastisol) with stainless steel inner spring Connectors: Polycarbonate Caps: Polyethylene with PVC (Plastisol) outer cover	Substantially equivalent. Biocompatibility confirmed for both devices in accordance with testing under ISO10993.
Sterilization	EtO sterilized, single-use, disposable, non-pyrogenic	EtO sterilized, single-use, disposable, non-pyrogenic	Same

I. Nonclinical Data:

All testing was conducted on finished, sterilized devices.

EtO sterilization was validated to SAL 10^{-6} using the overkill method, half-cycle technique in accordance with EN ISO 11135-1:2008 Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. EO and ECH residual levels were confirmed to comply with the limits under ISO 10993-7:2008. LAL Endotoxin testing to USP <85> verified that the endotoxin levels were well below the limits required for medical devices in contact with the cardiovascular system (≤0.5 EU/mL extract or ≤20 EU/device). Material-mediated pyrogenicity testing to USP <151> verified that the EtO sterilized CardioGard is pyrogen-free.

Biocompatibility testing was conducted in accordance with ISO 10993-1:2009, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing," for externally communicating devices in contact with circulating blood for limited (<24 hours) duration. Tests included cytotoxicity, irritation, sensitization, acute systemic toxicity, genotoxicity/mutagenicity, hemolysis, partial thromboplastin time, complement activation, and in-vivo thrombogenicity. All tests met the acceptance criteria of the applicable standard.

Packaging and device integrity tests were conducted at time 0 and after environmental conditioning, simulated transportation, and 3-year accelerated aging. All tests met the pre-defined acceptance criteria at all time periods.

Package integrity testing included the following:

- Peel Strength (Tensile) Test
- Burst Test
- Dye Penetration Test
- Package Label integrity

Device integrity testing included the following:

- Visual Inspection and Dimensional Verification
- Force at Break
- Tip force at break
- Pressure Drop
- Back pressure
- Liquid Leakage
- Tube kinking
- Tube bending
- Tube hardness
- Resistance to clamping
- Tube printing ink integrity

Dynamic hemolysis testing was conducted in an in vitro blood loop with bovine blood circulating at a net forward flow of 5 L/min for 6 hours. Test results demonstrated similar gradual increases in plasma free haemoglobin for the modified CardioGard Cannula as compared to a commercially available arterial cannula, the Medtronic Select 3D II (K043179).

The functional performance of the modified CardioGard Cannula was validated a simulated use test set-up with direct comparison to the predicate device. The results of this testing demonstrated substantially equivalent embolic particle capture for the modified CardioGard Cannula as compared to the original CardioGard Cannula when used in accordance with the instructions for use under test conditions simulating aortic manipulation, maximum flow rates, and typical flow rates used during the cardiopulmonary bypass procedure.

I. Conclusion

The information and testing presented in this 510(k) demonstrates that the modified CardioGard Emboli Protection Cannula is substantially equivalent to the original device cleared under K141465 because it has the same intended use, indications for use, mechanism of action, and principles of operation. Testing provided in this 510(k) confirms that the technological changes from the originally cleared CardioGard Cannula do not significantly affect the safety or efficacy of the device.