January 28, 2021

Kapp Surgical Instrument, Inc.
% William Mclain
Consultant
CRO Group, Inc
342 Main Street
Leola, Pennsylvania 17540

Re: K200289
Trade/Device Name: Michler-Kapp Cardiovascular Vent Catheter
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: December 28, 2020
Received: December 29, 2020

Dear William Mclain:

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,

Fernando Aguel
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200289

Device Name
Michler-Kapp Cardiovascular Vent Catheter

Indications for Use *(Describe)*
The Michler-Kapp Cardiovascular Vent Catheter is intended for use in venting the left heart during cardiopulmonary bypass surgery up to six hours or less.

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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K200289

Section 5

510(k) Summary

5.1 Submission Owner and Correspondent

Submission Owner

Kapp Surgical Instrument, Inc.
4919 Warrensville Center Rd
Cleveland, Ohio 44128 USA
Ph: 216-587-4400
Email: info@kappsurgical.com

Submission Correspondent

CRO Group, Inc.
342 E. Main Street, Suite 207
Leola, PA 17540
Contact: William McLain
Phone: 717-656-9656
E-Mail: bmclain@crogroup.com

5.2 Date Summary Prepared

January 30, 2020

5.3 Device Trade Name

Michler-Kapp Cardiovascular Vent Catheter

5.4 Device Common Name

Cardiovascular vent catheter.

5.5 Device Classification Name

Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass Classified as Class 2 at 21 CFR 870.4210, product code DWF.

5.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

The Michler-Kapp Cardiovascular Vent Catheter is substantially equivalent to both the Medtronic/ DLP 16 Fr Vent Catheter, Model 12116 cleared under K834352.

5.7 Description of the Device

This balloon-tipped left ventricular vent is intended to drain the left ventricle and left atrium of air, blood, and solid particles generated during surgery. The balloon-tipped LV vent is intended to be inserted through the open left atrium or through the right superior pulmonary vein and across the mitral valve into the left ventricle. In addition, it can be introduced directly into the left ventricle during mitral valve surgery. The design of the balloon-tipped LV vent focuses on ease of passage, position and safety. The soft balloon will inflate in the left ventricle, keeping the catheter tip below the mitral valve to ensure drainage of air, debris and blood from the left ventricle. In addition, the proximal holes will drain air, particulate debris, and blood from the left atrium.

Insertion Technique

Open Heart

With the heart on CPB, the heart is arrested by standard cardioplegic delivery following aortic cross-clamping, and the left atrium is surgically opened. Mitral valve surgery is performed and the surgeon places the LV Vent catheter. The catheter is inserted into the left ventricle and the balloon is inflated under direct vision. The left atrium is partially closed and the cross clamp is removed from the aorta and suction applied to the LV Vent catheter. As the heart starts beating, the vent remains on suction to remove air, blood, debris, etc. At the appropriate time deemed by the surgeon, the balloon is deflated, the catheter removed from the left ventricle and the left atrial suture line is completed, thus closing the heart.

Closed Heart

The catheter is placed through a purse string in the right superior pulmonary vein. The vent catheter is shaped into an “S” for ease of insertion. The catheter is inserted from the right superior pulmonary vein through the left atrium and the mitral valve into the left ventricle. The patient may or may not be on CBP at this point depending on surgeon preference. The surgeon may palpate for proper placement of the catheter. The stylet is removed and ejection of pulsitile blood from the proximal hub is confirmation of placement in the left ventricle. The balloon is inflated and suction is applied to begin venting. The procedure is completed and when venting is no longer necessary, the balloon is deflated, the vent catheter is removed and the purse string suture is tied.

The device has the following features.

Hub

A proximal hub is provided to give access to the balloon lumen and the suction lumen.

Double Lumen Extrusion with Suction Holes

The catheter tubing consists of a two–lumen extrusion providing separation between the balloon lumen and the suction lumen. A total of eighteen suction holes are located proximal and distal to the balloon to allow for the flow of blood, air and particulate debris.

Balloon

The balloon is intended to be filled with saline and has an approximate diameter of 1 inch. The purpose of the balloon is to position the catheter such that the tip is in the ventricle and the portion proximal to the balloon is in the atrium. The balloon is inflated in the left ventricle thus ensuring that the catheter can remain in place thus allowing the catheter to drain both the left ventricle and left atrium without repositioning.

Stylet with Thumb Tab

A shapeable stylet provides catheter stiffness during insertion. The stylet is removed by the thumb tab prior to use of the catheter.

Device Attributes

Table 5.1 contains a listing of the device attributes and key dimensions.

Table 5.1: Device Attributes

Feature	**Proposed Kapp Device**
Indication for use	Venting the left heart during cardiopulmonary bypass surgery of up to 6 hours.
Diameter	16 Fr
Length	16 in
Working Length	14 in
Positioning Balloon	Yes
Catheter Body Material	Polyurethane
Malleable guide wire	Yes
Vent Holes	Yes - distal tip
Pressure monitoring Lumen	No

5.8 Indication for Use

The Michler-Kapp Cardiovascular Vent Catheter is intended for use in venting the left heart during cardiopulmonary bypass surgery up to six hours or less

5.9 Technological Characteristics

Table 5.2 compares the technological characteristics between the proposed Michler-Kapp Cardiovascular Vent Catheter and the predicate Medtronic/DLP 16 Fr Vent Catheter, Model 12116.

Table 5.2: Comparison of Technological Characteristics

Feature	**Proposed Device - Michler-Kapp Cardiovascular Vent Catheter**	**Predicate Device - Medtronic/DLP 16 Fr Vent Catheter, Model 12116 (K834352)**
Indication for use	The Michler-Kapp Cardiovascular Vent Catheter is indicated for venting the left heart during cardiopulmonary bypass surgery of up to 6 hours.	This catheter is intended for use in venting the left heart during cardiopulmonary bypass surgery up to six hours or less.
Diameter	16Fr	16Fr
Length	16in	15in
Working Length	14in	13.5in
Positioning Balloon	Yes	No
Catheter Body Material	Polyurethane	PVC
Catheter CM Markings	Three marks indicating 10, 15, and 20cm from the distal tip	Individual mark representing 1 through 10cm from the proximal portion of the vent holes.
Hub Configuration	"Y" Configuration to provide fluid pathway and balloon inflation lumens	"Straight" configuration for fluid pathway
Malleable guide wire/Stylet	Yes - Removable	Yes - Embedded
Vent Holes	Yes 18 holes total on distal tip. Ten distal to balloon and 8 proximal to balloon.	Yes - 12 including distal tip.
Tip	Rounded and Closed - Radiopaque filler.	Rounded and Vented - No Filler
Pressure monitoring Lumen	No	No

There are no significant differences between the proposed and predicate devices in relation to indication for use, diameter, length/working length, and the presence of a pressure monitoring lumen. Differences are observed in relation to the presence of a positioning balloon, the catheter body materials, the meaning of CM markings, hub configurations, the configuration of malleable stylet, the configuration of vent holes and the design of the tip.

As described in further detail in the body of the submission, none of the differences are so significant that they present new questions of safety and effectiveness. To summarize:

Presence of a Positioning Balloon - The positioning balloon does not alter the use of the device with respect to its indication for use. Based on physician feedback, the presence of a positioning balloon and the increased length of the vent holes keeps the tip in place, away from the heart walls and reduces the need to reposition the balloon to vent the left heart. When compared to other devices intended to pass through the heart that contain balloons, the differences do not negatively impact safety and effectiveness nor do they introduce new types of safety and effectiveness questions.

Catheter Body Materials - Though the catheter materials are different they both result in a catheter design that is soft, atraumatic, and flexible. Safety and performance risks were mitigated through successful completion of bench testing, biocompatibility, and hemolysis testing as referenced below. Therefore, there is no negative impact on safety and effectiveness or substantial equivalence.

Meaning of CM Markings - Centimeter markings for the proposed device are relative to the tip of the catheter where markings for the predicate device are relative to the proximal end of the vent holes. There is no standard for the use of reference markings for these types of devices, so the user will quickly adapt to the meaning and be able to adjust the catheter positioning accordingly. Therefore, there is no negative impact on safety and effectiveness or substantial equivalence.

Hub Configurations - For both the proposed and predicate device, the primary function of the proximal hub is to provide the conduit for the vented blood back to the cardiopulmonary bypass machine. The main difference is that the proposed device hub is configured as a "Y" to allow for connection of a syringe for filling the positioning balloon. The presence of this additional connection does not affect the use or purpose of the hub and does not introduce any risks or new questions of safety or effectiveness. Therefore, there is no negative impact on safety and effectiveness or substantial equivalence.

Configuration of Malleable Stylet - Both the proposed and predicate devices have a malleable stylet used to impart a shape to the catheter to facilitate insertion. The main difference is that the stylet for the proposed device must be removed prior to initiating venting and the predicate device has an embedded stylet that remains in place. Vent catheters currently marketed are available in a variety of configurations with straight, pre-formed, and styletted configurations. Therefore, providing a product with a removable stylet does not introduce any risks or new questions of safety or effectiveness. Therefore, there is no negative impact on safety and effectiveness or substantial equivalence.

Configuration of Vent Holes - The proposed and predicate devices both contain vent holes. The proposed device has a total of 18 holes on distal tip: ten holes distal to the balloon and 8 proximal to the balloon. The distal-most tip of the proposed device is closed. The predicate device has a total of 12 tips at the distal end of the catheter. Eleven are circumferentially placed around the tip and one is located on the distal most portion of the catheter, i.e. the end of the device. Any risks related to the differences in holes has been mitigated through hemolysis testing referenced below. Therefore, there is no negative impact on safety and effectiveness or substantial equivalence.

Design of the Tip - The proposed device has a rounded, closed tip. The tip material is filled with radiopacifier. The predicate device, too, has a rounded tip, but it is open or vented and there is no radiopacifier. Any risks related to the differences in holes has been mitigated through

hemolysis testing referenced below. Therefore, there is no negative impact on safety and effectiveness or substantial equivalence.

5.10 Non-Clinical Testing

The following non-clinical tests were performed on devices that underwent full manufacturing, including sterilization.

- Liquid and Air Leakage
- Tubing Tensile Force
- Tubing to Y-connector Tensile Force
- Balloon inflation
- Suction
- Kink Testing,
- Flexibility Testing
- Hemolysis

5.11 Biocompatibilty

The following biocompatibility tests were completed:

- Cytotoxicity,
- Sensitization,
- Intracutaneous Reactivity,
- Acute Systemic Toxicity (including pyrogenicity assessment), and
- Hemocompatibility.

5.12 Clinical Testing

No clinical testing was performed in association with this submission.

5.13 Conclusions

The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is substantially equivalent to the legally marketed predicate device.