October 27, 2017

Medtronic, Inc.
Renee Cveykus
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE (MVS83)
Mounds View, Minnesota 55112

Re: K171979
Trade/Device Name: Tubing Pack
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: October 18, 2017
Received: October 19, 2017

Dear Renee Cveykus:

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 (DICE) 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 (DICE) 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)*

K171979

Device Name
Tubing Pack

Indications for Use *(Describe)*
This product is indicated for use in the extracorporeal circuit during cardiopulmonary bypass (CPB) surgical procedures.

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

Date Prepared: June 29, 2017

Submitter's Name and Address:

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Proprietary Name:

Models	**Description**
See Appendix 3	Tubing Pack

Device Name and Classification:

Trade Name:	Tubing Pack
Common Name:	Catheter, cannula and tubing, vascular, cardiopulmonary bypass
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing.
Classification Panel:	Cardiovascular
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Classification:	Class II

Predicate Device:
K171308 Tubing Pack

Device Description
Medtronic Tubing Packs are used in cardiopulmonary bypass procedures for connecting the primary devices of the bypass circuit. The functionality and intended use of these devices are the same as those for the listed in the Table 2-1.

Table 2-1: Tubing Packs Cleared

510(k) Number	Date of Clearance	Device
K800178	02/21/1980	Uncoated Tubing Packs
K883956	10/28/1988	Biomedicus Tubing Packs
K924529	06/23/1993	Signature Tubing Packs
K891687	05/31/1989	Carmeda Coated Tubing Packs
K012538	23/08/2001	Trillium Coated Tubing Packs
K113845	01/25/2012	Tubing, Connectors, and Accessories with Balance™ Biosurface
K122811	10/12/2012	Balance Coated Connector Components
K151523	07/16/2015	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
K171308	06/02/2017	Tubing Pack – New Packaging Trays

Indications for Use
There is no change to the intended use of the devices/components. The current Indications for Use statement for these devices is listed below:

The Medtronic Tubing Pack is indicated for use in the extracorporeal circuit during cardiopulmonary bypass (CPB) surgical procedures.

Comparison to Predicate Devices
When compared to the predicate device, the Tubing Packs have the same:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Base materials
- Method of sterilization and sterility assurance level
- Shelf life

- Coatings
- Biocompatibility

Addition of Components (Tubing and Connectors)

Medtronic Tubing Packs consist of coated and uncoated tubing, connectors and various medical devices that are pre-assembled into user-specified extracorporeal cardiopulmonary bypass perfusion circuits. Tubing Packs are intended for use within the extracorporeal blood pathway during cardiopulmonary bypass surgical procedures. Medtronic Tubing Packs are currently packaged into qualified clear tray and sterile packaging systems. This submission is to add additional tubing and connectors for use in Tubing Pack and is changing as part of continual process improvement efforts. The component additions include tubing and connectors that may be coated or uncoated. The coating types include: Cortiva, Trillium and Balance and these three types of coatings are identical to the cleared existing components for Tubing Packs (K891687, K012538 and K122811). The components being added do not have any changes in materials, technology or labeling than previously cleared components for Tubing Packs. These additional components are representative of currently cleared components and do not add any additional risk to patients therefore, Medtronic believes these components may be added to the Tubing Packs. All packaging components remain unchanged (peel pouches, ties, bands, trays, lids and shipper). There is no change to the sterile barrier, sterilization and test methods used for these components. The type of components being added are outlined in Table 2-2.

Table 2-2: Types of Components being Added

Component	Quantity	Uncoated	Coated		
			Cortiva	Trillium	Balance
Connectors	121	39	28	24	30
		Type: Cap, luer, stopcock, monitoring line, connectors			
Tubing	86	35	0	23	28
		Size: .085x.062x, .107x.040x, 1/2X1/8, 1/2x3/32x, 1/4X1/16, 3/16x1/16, and 5/16x3/32x			
Total	207				

A detailed list of the new components can be found within Appendix 2.

Summary of Performance and Biological Testing

Verification and validation testing demonstrated that the tubing and connectors are substantially equivalent to the predicate. Medtronic conducted the following testing for the tubing and connector components:

- Pressure Integrity
- Kink Resistance (Tubing)
- Pressure Decay
- Spallation (Tubing)
- Pull Force
- Tubing Life
- Biocompatibility

The testing completed was a representative of worse case testing for tubing and connectors and the verification results were leveraged based on most challenging components. Each of the components in scope of this submission were reviewed against the product specification and the following rationalization documentation was completed:

- Mechanical Requirements (10561942DOC)
- Coating Requirements (10552508DOC)
- Design Verification for Non-stacked conditioning and Pressure Integrity (10571289DOC)
- Biocompatibility per product specifications (10560838DOC)

Based on this evaluation Medtronic considers these tubing and connectors are substantially equivalent to the predicate.

Conclusion

Medtronic has demonstrated that the Tubing Pack with the additional components used in extracorporeal cardiopulmonary bypass perfusion systems is substantially equivalent to the predicate device based upon design, testing, and indications for use. The fundamental scientific principle, labeling and the intended use are unchanged because of this device modification.