DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 23, 2017

Medtronic Sofamor Danek, USA, Inc.
Julie Bassett
Regulatory Affairs Program Manager
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K163279
Trade/Device Name: Medtronic Transportation/Sterilization Cassettes
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: November 18, 2016
Received: November 21, 2016

Dear Julie Bassett:

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 yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K163279

Device Name
Medtronic Transportation/Sterilization Cassettes

Indications for Use *(Describe)*
The Medtronic Transportation/Sterilization Cassettes are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses. The Medtronic Transportation/Sterilization Cassettes are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap.

Sterilization validations for the worst case Medtronic Transportation/Sterilization Cassettes (22.75 x 11.26 x 5.5 inches) included implants and common surgical instruments such as rasps, drivers, trials, handles, inserters, probes, drills, etc. The validated total weight was 28.4lbs. The validated worst case loading configurations of the Medtronic Transportation/Sterilization Cassettes included the following worst case lumen dimensions:

- 363 x 1.575mm
- 247.5 x 4.1mm

Sterilization parameters

Cycle	Temperature	Exposure time	Minimum dry time
Gravity displacement	250°F (121°C)	30 Minutes	30 Minutes
Gravity displacement	270°F (132°C)	15 Minutes	30 Minutes
Gravity displacement	275°F (135°C)	10 Minutes	30 Minutes
Dynamic-air-removal (4 pre-conditioning pulses)	270°F (132°C)	4 Minutes	30 Minutes
Dynamic-air-removal (4 pre-conditioning pulses)	275°F (135°C)	3 Minutes	30 Minutes

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.

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510(k) SUMMARY

Medtronic Sofamor Danek
Medtronic Transportation/Sterilization Cassettes
January 2017

I. Company:

Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132
(800) 876-3133

Contact: Julie Bassett
Regulatory Affairs Program Manager
Direct Telephone: (901) 399-3248
Fax: (901) 346-9738

Date Prepared: January 25, 2017

II. Device:

Name of Device: Medtronic Transportation/Sterilization Cassettes

Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (21 CFR 880.6850)

Classification: Class II

Product Code: KCT

Predicate Device: K152241 – Medtronic Transportation/Sterilization Cassettes (SE 1/20/2016)
The predicate has not been subject of a design related recall.

III. Description:

The Medtronic Transportation/Sterilization Cassettes include cases, trays, lids, caddies, modules, or brackets fabricated from a variety of materials commonly used to enclose, protect, and organize Medtronic orthopedic or neurological non-sterile devices, which meet national or international standards. The Medtronic Transportation/Sterilization Cassettes are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap. The Medtronic Transportation / Sterilization Cassettes design consists of multiple components designed to be integrated into a single unit, which protects the interior components during transportation, sterilization, and storage. These components consist of: an outer base, internal individual trays with or without lids, caddies and an outer locking lid. The components if the Medtronic Transportation/Sterilization Cassettes are fabricated from intrinsically stable metals and thermoplastic polymers. All of the components of the Medtronic Transportation/Sterilization Cassettes are perforated with an evenly distributed hole pattern, and are designed to be used for steam sterilization. Since the Medtronic Transportation/Sterilization Cassettes are perforated, an FDA-cleared wrap must be used for sterilization and to maintain the sterility of the contents. The Medtronic Transportation/Sterilization Cassettes are designed to be used with standard autoclaves used in hospitals and healthcare facilities. As such, the Medtronic Transportation/Sterilization Cassettes are effective for containing devices during sterilization and have been designed to withstand repeated steam sterilization cycles.

No changes are being made to the Medtronic Transportation/Sterilization Cassettes from the cassettes cleared in K152241, SE 1/20/2016. The purpose of this 510(k) is to update the labeling, specifically the information for use (IFU). The IFU is being updated to add manual cleaning instructions and to centralize similar information within the IFU and avoid potential confusion.

Device List:

1850060 Case - Triple Generic Outer Base (22.74 x 11.260 x 5.040 inches)

1850064 Lid - Generic Outer Lid (22.75 x 11.260 x 0.470 inches)

7022101L Tray Lid (21 x 10.13 x 0.075 inches)

P1850061 Tray 1 (20.75 x 9.79 x 1.32 inches)

P1850062 Tray 2 (21 x 10.13 x 1.69 inches)

P1850063 Tray 3 (21 x 10.13 x 1.38 inches)

7059532 Large Caddy (9.47 x 6.37 x 1.3 inches)

7059532L Large Lid (5.85 x 4.725 x 0.095 inches)

P9213018 Small Caddy (2 x 1.5 x 1.025 inches)

P9213018 Small Lid (2 x 1.29 x 0.095 inches)

IV. Indications For Use:

The Medtronic Transportation/Sterilization Cassettes are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses. The Medtronic Transportation/Sterilization Cassettes are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap.

Sterilization validations for the worst case Medtronic Transportation/Sterilization Cassette (22.75 x 11.26 x 5.5 inches) included implants and common surgical instruments such as rasps, drivers, trials, handles, inserters, probes, drills, etc. The validated total weight was 28.4lbs. The validated worst case loading configurations of the Medtronic Transportation/Sterilization Cassette included the following worst case lumen dimensions:

- 363 x 1.575mm
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Sterilization parameters

Cycle	Temperature	Exposure time	Minimum dry time
Gravity displacement	250°F (121°C)	30 Minutes	30 Minutes
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Dynamic-air-removal (4 pre-conditioning pulses)	275°F (135°C)	3 Minutes	30 Minutes

V. Comparison of Technological Characteristics:

Since there have been no changes to the Medtronic Transportation/Sterilization Cassettes, the technological characteristics for the cassettes remain unchanged from those characteristics cleared in K152241, SE 1/20/2016. In addition, modifications to the device labeling do not impact the technical characteristics of the Medtronic Transportation/Sterilization Cassettes. As shown in **Table 1: Substantial Equivalence – Comparison of Technological Characteristics for the Predicate and Subject Medtronic Transportation/Sterilization Cassettes** and **Table 2: Substantial Equivalence – Comparison of Performance Data for the Predicate and Subject Medtronic Transportation/Sterilization Cassettes**., the Medtronic Transportation/Sterilization Cassettes in this 510(k) submission are identical to the Medtronic Transportation / Sterilization Cassettes cleared in K152241, SE 1/20/2016.

Table 1: Substantial Equivalence – Comparison of Technological Characteristics for the Predicate and Subject Medtronic Transportation/Sterilization Cassettes

Feature	Predicate Device	Subject Device
Trade Name	Medtronic Transportation/Sterilization Cassettes	Identical
Fundamental Scientific Technology	Sterilization Cassette	Identical

Feature	Predicate Device	Subject Device
Intended Use	The Medtronic Transportation/Sterilization Cassettes are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses. The Medtronic Transportation/Sterilization Cassettes are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap.	Identical
Product Code	KCT	Identical
Material Composition	Thermoplastic polymers, aluminum, and stainless steel	Identical
Design	A base, a lid with a locking latch, and individual inserts	Identical
Dimensions	The greatest challenge dimension was assessed to be: 22.75 x 11.26 x 5.51 inches The inserts are offered in different sizes	Identical
Configuration	Perforated bases, lids, and inserts	Identical
Air Permeance	Yes	Identical
Percent Perforation	Evenly distributed hole pattern.	Identical
Sterilization Method	Pre-Vacuum and Gravity Displacement	Identical
Reusable	Yes	Identical

Table 2: Substantial Equivalence – Comparison of Performance Data for the Predicate and Subject Medtronic Transportation/Sterilization Cassettes

Feature	Predicate Device	Subject Device
Sterilant Penetration	Yes	Identical
Microbial Barrier Properties	To be used with an FDA approved sterilization wrap	Identical
Material Compatibility with Sterilization Method	Materials are compatible with sterilization method	Identical
Toxicological Properties	Materials are biocompatible	Identical

VI. Performance Data:

Biocompatibility:

No changes are being made to the Medtronic Transportation/Sterilization Cassettes – only the labeling is being updated; therefore, the original biocompatibility data still applies.

Verification/Validation Testing:

No changes are being made to the Medtronic Transportation/Sterilization Cassettes – only the labeling is being updated; therefore, the original verification/validation data still applies.

However, due to the addition of the manual cleaning instructions for the Medtronic Transportation/Sterilization Cassettes, a cleaning validation study was performed. The cleaning validation study demonstrated that the manual cleaning parameters were effective and will adequately clean Medtronic Transportation/Sterilization Cassettes.

VII. Conclusion:

In conclusion, the subject Medtronic Transportation/Sterilization Cassettes are substantially equivalent to predicate device Medtronic Transportation/Sterilization Cassettes cleared in K152241. Based on the intended use, technological characteristics, and performance data, the subject Medtronic Transportation / Sterilization Cassettes are substantially equivalent and are as safe and as effective as the legally marketed predicate device.