October 15, 2019

Medtronic Sofamor Danek USA, INC.
Elizabeth Hamilton
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K190840
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: September 12, 2019
Received: September 17, 2019

Dear Elizabeth Hamilton:

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 Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K190840

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. The Medtronic Transportation Sterilization Cassettes are intended for transport of non-sterile loads.
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 28.6lbs. 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

Device list:
- P1850078 Generic Triple Outer Base (22.74×11.26×5.04 inches)
- P1850079 Generic Outer Lid (22.75×l1.26×.470 inches)
- 7022101L Tray Lid (21.00×10.13×.075 inches)
- P1850010 Tray 1 (20.71×9.82×4.4 inches)
- P1850011 Tray 2 (18.81×9.50×2.8 inches)
- P1850012 Tray 3 (18.30×9.20×.840 inches)
- P1850013 Large Caddy (9.4×5.3×1.49 inches)
- P1850014 Large Lid (9.40×5.045×.095 inches)
- P1850015 Small Caddy (2.00×1.50×1.025 inches)
- P1850016 Small Lid (2.0xl.245x.095 inches)

Sterilization Parameters

Cycle	Temperature	Exposure time	Minimum dry time
Dynamic-air-removal	270°F (132°C)	4 Minutes	30 Minutes
Dynamic-air-removal	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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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

MEDTRONIC
Medtronic Transportation / Sterilization Cassettes

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact Person	Elizabeth Hamilton Regulatory Affairs Specialist Direct Telephone: (901) 399-3395
Date Prepared	September 27, 2019
Name of Device	Medtronic Transportation/ Sterilization Cassettes
510(k) Number	K190840
Common Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification Name	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (21 CFR 880.6850)
Classification	Class II
Product Codes	KCT
Predicate Device	Medtronic Transportation /Sterilization Cassettes (K152241, S.E. 1/20/2016)
Description of Device	The Medtronic Transportation/Sterilization Cassettes include cases, trays, lids, caddies, modules, or brackets fabricated from a variety of materials which meet national or international specifications and are commonly used to enclose, protect, and organize Medtronic orthopedic or neurological non-sterile devices. 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.

<table>
<tr>
<td>Indications for Use</td>
<td>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. The Medtronic Transportation Sterilization Cassettes are intended for transport of non-sterile loads.
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
247.5 X4.1 mm

Device List
P1850078 Generic Triple Outer Base (22.74 X 11.26 X 5.04 inches)
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Sterilization Parameters

<table>
<tr><th>Cycle</th><th>Temperature</th><th>Exposure Time</th><th>Minimum Dry Time</th></tr>
<tr><td>Dynamic-air-removal</td><td>270°F (132°C)</td><td>4 Minutes</td><td>30 Minutes</td></tr>
<tr><td>Dynamic-air-removal</td><td>275°F (135°C)</td><td>3 Minutes</td><td>30 Minutes</td></tr>
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<tr>
<td>Technological Characteristics</td>
<td>Technological Characteristics Comparison Table:

Shown below is a comparison of the subject device with the predicate device.

Table 2: Comparison of Technological Characteristics of Medtronic Transportation/ Sterilization Cassettes with Predicate.</td>
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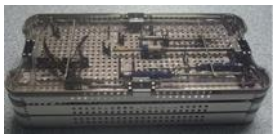
Feature	Subject Device (K190840)	Predicate Device (K152241)	Comparison
Picture	 Medtronic Transportation /Sterilization Cassettes  Nested Capability of the Individual Trays within the Medtronic Transportation/Sterilization Cassettes	 Medtronic Transportation/ Sterilization Cassettes  Stacking capability of Individual Trays	similar
Trade Name	Medtronic Transportation/ Sterilization Cassettes	Medtronic Transportation/ Sterilization Cassettes	identical
Fundamental Scientific Technology	Sterilization Cassette	Sterilization Cassette	identical
Intended use	The Medtronic Transportation/ Sterilization Cassettes are intended for use in health care facilities to organize, enclose, sterilize, transport and store medical devices 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. The Medtronic Transportation Sterilization Cassettes are intended for transport of non-sterile loads.	The Medtronic Transportation/ Sterilization Cassettes are intended for use in health care facilities to organize, enclose, sterilize, transport and store medical devices 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. The Medtronic Transportation Sterilization Cassettes are intended for transport of non-sterile loads	identical
Product Code	KCT	KCT	identical

Material Composition	Radel®, SANTOPRENE™, Silicone, Aluminum, Nylon, Polypropylene and Stainless Steel	Radel®, SANTOPRENE™, Silicone, Aluminum, Nylon, Polypropylene and Stainless Steel	identical
Device Design	A base, a lid with a locking latch and individual inserts in nested design	A base a lid with a locking latch and individual inserts stacked	similar
Dimensions	22.750× (W)11.26 ×(H)5.51 (outer case) The inserts are offered in different sizes	22.750× (W)11.26 ×(H)5.51 (outer case) The inserts are offered in different sizes	identical
Weight	28.6lbs	28.4lbs	different
Configuration	Perforated bases, lids and inserts	Perforated bases, lids and inserts	identical
Percent perforation	1.304% greatest challenge component	4.73% greatest challenge component	different
Sterilization Method	Pre- Vacuum (Steam)	Pre-Vacuum(Steam) Gravity Displacement (Steam)	similar
Sterilization Parameters	[1]Dynamic- Air Removal (4 Pre-conditioning pulses) • 132°C(270°F) 4 minutes • 135°C(275°F) 3 minutes • 134°C(273°F) 3 minutes [1] Note "Dynamic Air Removal" is also commonly referred to as "Pre-vacuum"	Gravity Displacement Minimum Dry Time: 30 mins • 121°C(250°F) 30 minutes • 132°C(270°F) 15 minutes • 135°C(275°F) 10 minutes <u>Pre-Vacuum</u> Minimum Dry Time: 30 mins • 132° C(270°F) 4 minutes • 134°C(273°F) 4 minutes • 135°C (275°F) 3 minutes	similar
Reusable	Yes	Yes	same

<table>
<tr><td></td><td>The results from the comparison table demonstrate that the subject device and the predicate device have similar technological characteristics.</td></tr>
<tr><td>Performance Testing</td><td>Shown below is a description of the performance testing performed to demonstrate and verify that the subject device meets the acceptance criteria found in the standard and test methodology.

Table 3: Nonclinical Performance Testing

<table>
<tr><th>Test Methodology</th><th>Purpose</th><th>Acceptance criteria</th><th>Results</th></tr>
<tr><td>Distribution Simulation Validation For the New Outercase
Per ASTM D4169-14</td><td>The objective of this project was to evaluate the ability of the new outer case for Medtronic to withstand the distribution environment</td><td>Outer cases and inner trays will be visually inspected after each distribution cycle for obvious damages.
Outer cases will fail the test protocol if there is obvious
Fit and function of devices were evaluated post distribution testing to show devices within the brackets still meet the surgical intent.</td><td>Pass</td></tr>
<tr><td>Biocompatibility Testing per ISO 10993</td><td>Evaluate patient contact and harm associated to materials</td><td>Not applicable to subject devices; as device does not have direct patient contact. However medical devices that are used in conjunction with sterilization cassettes are tested</td><td>Pass</td></tr>
<tr><td>ANSI/AMMI ISO 17665-1</td><td>The objective of this study is to demonstrate that steam sterilization processes consistently</td><td>(SAL) of 10^{-6}</td><td>Pass</td></tr>
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</td></tr>
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		achieves a sterility assurance level (SAL) of 10^{-6}		
Conclusion	The conclusion drawn from the nonclinical tests demonstrate that the, Medtronic Transportation/Sterilization Cassette devices, is as safe, as effective, and performs as well as or better than legally marketed predicate device (K152241).			