



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 20, 2016

Medtronic Sofamor Danek
Ms. Victoria Scheitlin
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K152241

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: December 18, 2015
Received: December 21, 2015

Dear Ms. Scheitlin:

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" (21CFR 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152241

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; it is 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
- 247.5 x 4.1mm

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)

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.

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510(k) SUMMARY

MEDTRONIC Sofamor Danek
Medtronic Transportation/Sterilization Cassettes
January 19, 2015

- I. Company:** Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132
(800) 876-3133
- Contact: Victoria Scheitlin
Regulatory Affairs Specialist
Telephone: (901) 344-0706
- Fax: (901) 346-9738
- Date Prepared: January 19, 2015
- II. Device:**
- Name of Device: Medtronic Transportation/Sterilization Cassettes
- 510(k) Number: K152241
- Classification: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (21 CFR 880.6850)
- Name:
- Class: II
- Product Code: KCT
- III. Predicate Devices:**
- K131455 (Primary Predicate) – Restore Modular Sterilization Tray System (S.E. 08/30/2013)
 - K033222 – Olympus Sterilization Trays (S.E. 08/02/2004)
 - K993535 – Metapak Multi-Purpose Instrument Tray (S.E. 12/07/2001)
 - K120947 – THS Sterilization Tray (S.E. 10/17/2012)

Additionally, this submission contains a reference device K130720 – Synthes Reusable Sterilization Container Systems (S.E. 08/14/2014). The Synthes Reusable Sterilization Container Systems are fabricated from similar materials to those used in the Medtronic Transportation/Sterilization Cassettes, specifically nylon and polypropylene. The reference device also has a similar sterilization method, design configuration options and sizes.
The predicates have not been subject to a design related recall that Medtronic is aware.

- IV. 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 specifications. 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 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 of 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 sterilization via steam sterilization. Since the Medtronic Transportation/Sterilization Cassettes are perforated, an FDA cleared wrap must be used for sterilization purposes 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. Thus allowing the Medtronic Transportation/Sterilization Cassettes to be effective for sterilization and are designed such that they withstand the environment of repeated steam sterilization cycles.

V. 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; it is 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
- 247.5 x 4.1mm

Device List:

- 1850060 Case - Triple Generic Outer Base (22.74 x 11.260 x 5.040 inches)
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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)	270°F (132°C)	4 Minutes	30 Minutes
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VI. Comparison of Technological Characteristics and Performance Data with the Predicate Devices:

Table 2 and **Table 3** display the comparison of the Medtronic Transportation/Sterilization Cassettes compared against the predicates. The comparison analysis was performed to support the substantial equivalence of the Medtronic Transportation/Sterilization Cassettes and trays to the listed predicates.

The Medtronic Transportation/Sterilization Cassettes were validated to be the greatest challenge (worst case). The Medtronic Transportation/Sterilization Cassettes described within this submission were determined to be the worst case configuration for sterilization and reprocessing due to the weight, percent perforation, and the number of trays and caddies included within the final configuration in the entirety.

Table 2: Substantial Equivalence – Comparison of Medtronic Transportation/Sterilization Cassettes with Predicates on Technological Characteristics

Feature	Subject Device	K131455 (Primary Predicate)	K033222	K993535	K120947
1. Trade Name	Medtronic Transportation/Sterilization Cassettes	Restore™ Modular Sterilization Tray System	Olympus Sterilization Trays	Metapak Multi-Purpose Instrument Tray	THS Sterilization Tray
2. Fundamental Scientific Technology	Sterilization Cassette	Same	Same	Same	Same
2. 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.	The Restore™ Modular Sterilization Tray System is intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses when used in conjunction with a FDA cleared sterilization wrap.	The Olympus sterilization trays are intended to be used to enclose Olympus medical devices including hand instruments, trocars, camera heads, adapter, and endoscopes to be sterilized by a health care provider. It is intended to allow steam sterilization of the enclosed medical	The Riley Metapak Multi-Purpose Instrument Tray is used for loading surgical instruments in order to conveniently organize, sterilizes, transports and store the instruments between use. The Riley Metapak Multi-Purpose Instrument Tray can be used in pre-vacuum steam and ethylene oxide	The THS Sterilization Tray is used to enclose, protect, and organize the THS scopes, diagnostic sheath, and associated accessory components, and to facilitate the sterilization process by allowing sterilant penetration and air removal when used in conjunction with an approved sterilization

Feature	Subject Device	K131455 (Primary Predicate)	K033222	K993535	K120947
			device.	sterilization	wrap.
3. Product Code	KCT	KCT	KCT	KCT	KCT
4. Material Composition	Thermoplastic polymers, aluminum, and stainless steel	Thermoplastic polymers, aluminum, and stainless steel	Thermoplastic polymers and stainless steel	Thermoplastic polymers, aluminum, and stainless steel	Thermoplastic polymers, aluminum, and stainless steel
5. Design	A base, a lid with a locking latch, and individual inserts	A base, a lid, and individual inserts	A bottom, a lid with locking tabs, and individual inserts	A base, a lid with latches, and individual inserts	A base, a lid, and individual inserts
6. Dimensions	<p>The greatest challenge dimension was assessed to be: 22.75 x 11.26 x 5.51 inches</p> <p>The inserts are offered in different sizes</p>	<p>10 x 20 x 4 inches or a 10 x 10 x 4 inches tray with a lid.</p> <p>The inserts are offered in different sizes (not specified in summary.)</p>	<p>A wide variety of dimensions and configurations ranging from: 405 x 95 x 200mm (16 x 4 x 8 inches) to 665 x 52 x 204mm (26 x 2 x 8 inches)</p>	<p>Bases and lids are offered in 3 sizes:</p> <ul style="list-style-type: none"> • 22 x 10 x 6 inches • 22 x 10 x 4 inches • 26 x 10 x 6 inches <p>Insert trays are offered in 2 sizes:</p> <ul style="list-style-type: none"> • 21 x 9.5 x 2.5 inches • 10 x 9.5 x 2.5 inches <p>The inserts are offered in different sizes (not specified in summary.)</p>	<p>The “base” tray is 17.3 x 7.25 x 4 inches</p> <p>The inserts are offered in different sizes (not specified in summary.)</p>

Feature	Subject Device	K131455 (Primary Predicate)	K033222	K993535	K120947																								
7. Configuration	Perforated bases, lids, and inserts	Perforated bases, lids, and inserts	<ul style="list-style-type: none"> Perforated or Solid Lids Perforated Bottoms 	Perforated bases, lids, and inserts	Perforated bases, lids, and inserts																								
8. Air Permeance	Yes	Yes	Yes	Yes	Yes																								
9. Percent Perforation	Evenly distributed hole pattern.	Evenly distributed hole pattern.	Evenly distributed hole pattern.	Evenly distributed hole pattern.	Evenly distributed hole pattern.																								
10. Sterilization Method	<ul style="list-style-type: none"> Pre-Vacuum Gravity Displacement 	High Vacuum Steam	Pre-vacuum Steam	<ul style="list-style-type: none"> Pre-vacuum Steam Ethylene Oxide Sterilization 	<ul style="list-style-type: none"> Pre-Vacuum Gravity Displacement 																								
11. Sterilization Parameters	<table border="1"> <thead> <tr> <th>Cycle</th> <th>Temperature</th> <th>Exposure time</th> <th>Minimum dry time</th> </tr> </thead> <tbody> <tr> <td>Gravity Displacement</td> <td>250°F (121°C)</td> <td>30 Minutes</td> <td>30 Minutes</td> </tr> <tr> <td>Gravity Displacement</td> <td>270°F (132°C)</td> <td>15 Minutes</td> <td>30 Minutes</td> </tr> <tr> <td>Gravity Displacement</td> <td>275°F (135°C)</td> <td>10 Minutes</td> <td>30 Minutes</td> </tr> <tr> <td>Dynamic-Air-Removal (4 Pre-conditioning pulses)</td> <td>270°F (132°C)</td> <td>4 Minutes</td> <td>30 Minutes</td> </tr> <tr> <td>Dynamic-Air-Removal (4 Pre-conditioning pulses)</td> <td>275°F (135°C)</td> <td>3 Minutes</td> <td>30 Minutes</td> </tr> </tbody> </table>	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	<p>High Vacuum (pre-vacuum, three pulse, standard): Temp: 270° F</p> <p>Exposure Time: 4 Minutes Cycle Dry Time (wrapped): 20 Minutes (minimum)</p> <p>Cool Time: Varies according to load contents</p>	<p>Prevacuum Steam: 132°C - 134°C 5 minutes minimum</p> <p>Drying Time: 10 –20 minutes as needed.</p>	<p>Not provided in 510(k) Summary</p>	<p>Pre-Vacuum Parameters: 270°F for 4 minutes</p> <p>Pre-Vacuum Dry Time: 30 minutes Gravity Parameters: 250°F for 30 minutes</p> <p>Gravity Dry Time: 30 minutes</p>
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12. Reusable	Yes	Yes	Yes	Yes	Yes																								

Table 3: Substantial Equivalence – Comparison of Medtronic Transportation/Sterilization Cassettes with Predicates on Performance Data

Feature	Subject Device	K131455 (Primary Predicate)	K033222	K993535	K120947
1. Sterilant Penetration	Yes	Yes	Yes	Yes	Yes
2. Microbial Barrier Properties	To be used with an FDA approved sterilization wrap	To be used with an FDA approved sterilization wrap	To be used with an FDA approved sterilization wrap	No claims are made in the summary	No claims are made in the summary
3. Material Compatibility with Sterilization Method	Materials are compatible with sterilization method	Yes	Compatible to Steam Sterilization at 132°C	Yes	Yes
4. Toxicological Properties	Materials are biocompatible	Materials are biocompatible	Materials are biocompatible	Not stated in summary	Not stated in summary

No new issues of safety or effectiveness have been raised, based on the nonclinical tests performed. There are no differences between the subject and predicate devices. The subject device is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate devices.

VII. Performance Testing

The testing of the Medtronic Transportation/Sterilization Cassettes is supported by packaging testing, sterilization validations, and biocompatibility testing. . The performance testing performed on the Medtronic Transportation/Sterilization Cassettes was tested and validated to the greatest challenge (worst case).

Medtronic Transportation/Sterilization Cassettes were evaluated on the ability to withstand the distribution environment. The distribution testing concluded that the Medtronic Transportation/Sterilization Cassettes were able to with stand the distribution environment. The testing was conducting in accordance with ASTM D4169: 2009 – *“Standard Practice for Performance Testing of Shipping Containers and Systems”*.

To establish substantial equivalence with a predicate device, the performance testing was conducted to confirm that SAL (10^{-6}) sterility level was achieved at the validated sterilization parameters. The testing was conducting in accordance with the following standards:

- AAMI TIR39: 2009 *“Guidance On Selecting A Microbial Challenge And Inoculation Sites For Sterilization Validation Of Medical Devices”*
- AAMI TIR30: 2011 *“A Compendium Of Processes, Materials, Test Methods, And Acceptance Criteria For Cleaning Reusable Medical Devices”*
- AAMI TIR17: 2008 *“Compatibility Of Materials Subject To Sterilization”*
- AAMI TIR12: 2010 *“Designing, Testing, And Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities: A Guide For Medical Device Manufacturers”*
- ANSI/AAMI ST81: 2004 *“Sterilization Of Medical Devices— Information To Be Provided By The Manufacturer For The Processing Of Resterilizable Medical Devices”*
- ANSI/AAMI ST79: 2010 (R) 2014 *“Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities - Incorporates ”*
- ANSI/AAMI/ISO TIR17665-2: 2009 *“Sterilization Of Health Care Products — Moist Heat — Part 2”*
- ANSI/AAMI/ISO 17665-1: 2006 *“Sterilization Of Health Care Products-Moist Heat-Part 1: Requirements For The Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices”*
- ISO 17664: 2004 *“Sterilization Of Medical Devices Information To Be Provided By The Manufacturer For The Processing Of Resterilizable Medical Device”*

- ANSI/AAMI/ISO 14161: 2009 “*Sterilization Of Health Care Products — Biological Indicators — Guidance For The Selection, Use And Interpretation Of Results* ”
- ANSI/AAMI/ISO 11737-2: 2009 “*Sterilization Of Medical Devices — Microbiological Methods — Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process* ”

The Medtronic Transportation/Sterilization Cassettes do not have direct patient contact. The Medtronic Transportation/Sterilization Cassette components are fabricated from a variety of intrinsically stable metals and thermoplastics. Based on the testing performed, should substances transfer from the Medtronic Transportation/Sterilization Cassettes they would not present a chemical hazard. The assessment was conducted based on ISO 10993-1:2009 “Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process”.

VIII. Conclusion:

Results of performance testing, and the similarities with legally marketed predicate devices it can be concluded that the Medtronic Transportation/Sterilization Cassettes will perform to the intended use. Medtronic believes that the subject Transportation/Sterilization Cassettes is substantially equivalent to the following predicates:

- Predicate 1 – Restore Modular Sterilization Tray System K131455 (S.E. 08/30/2013)
- Predicate 2 – Olympus Sterilization Trays K033222 (S.E. 08/02/2004)
- Predicate 3 – Metapak Multi-Purpose Instrument Tray K993535 (S.E. 12/07/2001)
- Predicate 4 – THS Sterilization Tray K120947 (S.E. 10/17/2012)
- Reference Device – K130720 – Synthes Reusable Sterilization Container Systems (S.E. 08/14/2014) for the fabrication of nylon and polypropylene as materials.

No new issues of safety or effectiveness have been raised, based on the nonclinical tests performed. The subject device is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate devices. Therefore, the Medtronic Transportation/Sterilization Cassettes are considered to be substantially equivalent to the predicate devices, Class II (21 CFR 880.6850), Product code KCT.