**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

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

May 16, 2017

Medtronic Sofamor Danek USA, Inc.
Ms. Claire Evans
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K163181
Trade/Device Name: TRANSLACE™ Spinal Tethering System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: April 18, 2017
Received: April 19, 2017

Dear Ms. Evans:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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)*
K163181

Device Name
TRANSLACE™ Spinal Tethering System

Indications for Use *(Describe)*

The TRANSLACE™ Spinal Tethering System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic, congenital and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The TRANSLACE™ Spinal Tethering System may also be used in conjunction with other medical implants made of similar metals whenever "wiring" may help secure the attachment of other implants.

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
## TRANSLACE™ Spinal Tethering System

**April 2017**

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| Submitter: | Medtronic Sofamor Danek, USA Inc.<br>1800 Pyramid Place<br>Memphis, Tennessee 38132<br>Telephone: (901)396-3133<br>Fax: (901) 346-9738 |
| Contact Person | Claire Evans<br>Senior Regulatory Affairs Specialist<br>Direct Telephone: (901)399-0804 |
| Date Prepared | April 18, 2017 |
| Name of Device | TRANSLACE™ Spinal Tethering System |
| Common Name | Connector, Tether, Tensioner |
| Trade Name | TRANSLACE™ Spinal Tethering System |
| Regulatory Class, Regulation Number, Regulation Name, and Device Product Code | • Class II<br>• 21 CFR 888.3010<br>o Bone Fixation Cerclage<br>o OWI |
| Predicate Devices | K110348 Zimmer Universal Clamp (S.E. 8/11/2011) – Primary Predicate<br>K143350 K2M Nile Alternate Fixation System (S.E. 2/25/2015)<br>*The predicates have not been subject to a design related recall.* |
| Reference Devices | K101074 CD Horizon® Spinal System (S.E. 6/22/2010)<br>K152338 Vertex Reconstruction System (S.E. 10/28/2015)<br>K152241 Medtronic Transportation/Sterilization Cassette System (S.E.1/20/2016) |
| Description of Device | The TRANSLACE™ Spinal Tethering System consists of temporary implants and a reusable instrument for use in orthopedic spinal surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. This system will allow the spine to be secured to a rod construct without the use of a bone screw. It will act as an alternative to sublaminar wires and hooks. |

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| | This system consists of:<br>• Connector<br>• Tether<br>• Tensioner<br>• Accessory – system specific tray which may be used to transport and sterilize the subject instruments.<br>The subject TRANSLACE™ Spinal Tethering System devices will be available in similar sizes as the predicate systems. |
| Indications for Use | The TRANSLACE™ Spinal Tethering System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:<br><br>1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;<br>2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic, congenital and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis, and spondylolisthesis;<br>3. Spinal degenerative surgery, as an adjunct to spinal fusions.<br><br>The TRANSLACE™ Spinal Tethering System may also be used in conjunction with other medical implants made of similar metals whenever "wiring" may help secure the attachment of other implants. |
| Comparison of Technological Characteristics with the Predicate Devices: | The TRANSLACE™ Spinal Tethering System has the same fundamental technology; polyester, titanium and stainless steel material as the predicate devices. The predicate and subject devices are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the spine.<br>• K110348 Zimmer Universal Clamp (S.E. 8/11/2011) – Primary Predicate<br>• K143350 Nile Alternative Fixation System (S.E. 2/25/2015) |

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| Performance Data: | The following performance data were provided in support of substantial equivalence.<br><br>**Biocompatibility**<br>The biocompatibility evaluation for the TRANSLACE™ Spinal Tethering System devices was conducted in accordance with FDA's Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" issued June 16, 2016.<br><br>The subject implants are temporary implants and will be classified as permanent, >30 day body contact according to with FDA's Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" issued June 16, 2016.<br><br>The subject Connector is manufactured from identical materials as the predicate devices, in accordance with the following ASTM standard:<br><br>• ASTM F136 – Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications<br><br>The subject Tether is manufactured from polyester and titanium. The following tests have been conducted to ensure biocompatibility:<br>• Chemical Characterization<br>• Cytotoxicity<br>• Acute Systemic Toxicity<br>• Material Mediated Pyrogenicity<br>• Implantation<br>Based on the results, no additional testing was required.<br><br>The subject instrument is an external communicating devices and is classified as limited, up to 24 hours of body contact according to with FDA's Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of |

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| | Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" issued June 16, 2016. This instrument is manufactured from the same medical grade stainless steel as the predicate devices in accordance with the following ASTM standards:<br>• ASTM F899 – Standard Specification for Wrought Stainless Steel for Surgical Instruments<br>• ASTM A564 – Standard Specification for Hot-Rolled and Cold Finished Age-Hardening Stainless Steel Bars and Shapes<br>• ASTM A693 – Standard Specification for Precipitation-Hardening Stainless and Heat-Resisting Steel Plate, Sheet and Stripe<br>• ASTM A276 – Standard Specification for Stainless Bars and Shapes<br><br>The system specific tray used for shipment and sterilization of instruments is manufactured from stainless steel, aluminum, nylon coated stainless steel, radel, polypropylene with the brackets securing the instruments into the case/tray made of silicone and/or nylon coated stainless steel and/or polypropylene. These materials are non-patient contacting and indirect patient contacting and are the same materials as the predicate. Therefore, no new biocompatibility testing is required.<br><br>**Mechanical Testing**<br>In accordance with, Guidance for Industry and FDA Staff – Spinal System 510(k)'s", Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. A combination of engineering rationales and testing were used to establish substantial equivalence. The following bench testing was completed and the results of these tests demonstrated the substantial equivalence of the subject devices to the predicates.<br>• Tether Grip Static Testing (ASTM F1798)<br>• Tether Grip Fatigue Testing (ASTM F1798)<br>• Static Axial Grip Testing (ASTM F1798)<br>• Static Axial Rotational Grip Testing (ASTM F1798)<br>• Compression Fatigue Testing (ASTM F1717) |

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| | • Static Weld Testing<br>The following validation activities were completed and met the predetermined acceptance criteria.<br>• Cadaver and/or True-Trainer (Sawbone) Validation Testing<br>• Instructions to Support Reprocessing Validation. |
| Conclusion: | Based on the risk analysis, test results, and additional supporting documentation provided in the pre-market notification, the subject TRANSLACE™ Spinal Tethering System is as safe and effective as the following predicates:<br>• K110348 Zimmer Universal Clamp (S.E. 8/11/2011) – Primary Predicate<br>• K143350 Nile Alternative Fixation System (S.E. 2/25/2015) |