DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek, USA, Incorporated
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

March 28, 2016

Re: K160528
Trade/Device Name: ANATOMIC PEEK™ PTC Cervical Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: March 8, 2016
Received: March 10, 2016

Dear Mr. Grant:

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 Parts 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,

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)*

K160528

Device Name

ANATOMIC PEEK™ PTC Cervical Fusion System

Indications for Use *(Describe)*

The ANATOMIC PEEK™ PTC Cervical Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The ANATOMIC PEEK™ PTC Cervical Fusion System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach from the C2-C3 disc space to the C7-T1 disc space using autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The ANATOMIC PEEK™ PTC Cervical Fusion System is to be used with supplemental fixation. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral cage.

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.

510(k) Summary – K160528
Medtronic Sofamor Danek
ANATOMIC PEEK™ PTC CERVICAL FUSION SYSTEM
March 24, 2016

Submitter	Medtronic Sofamor Danek USA 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact(s)	Lee Grant Distinguished Regulatory Affairs Advisor Direct Telephone – 901-344-0807
Date Prepared	March 24, 2016
Common Name	Cervical Interbody Cage
Regulatory Class **Regulation Number** **Regulation Name and Device Product Classification Code**	Class II 888.3080 Intervertebral Body Fusion Device ODP
Predicate Devices	1) Valeo Spacer System-C and VALEO® II-C (K142264, SE 12/08/14 – Primary Predicate) **2)** ANATOMIC PEEK™ PTC Cervical Fusion System (K133653, SE 04/28/14) The predicate devices have not been subject to a design related recall
Description of Device	The ANATOMIC PEEK™ PTC Cervical Fusion System is designed for use as a cervical interbody fusion device. These devices are manufactured from polyetheretherketone (PEEK OPTIMA™) each containing a commercially pure titanium coating along with tantalum markers. This device is to be used with autogenous and/or allogenic bone graft material (cancellous and/or corticocancellous bone chips).The ANATOMIC™ PEEK PTC Cervical Fusion System consists of hemi-cylindrical cages of various widths, heights and depths. The hollow geometry of the implants allows them to be packed with autogenous or allogenic bone graft (cancellous and/or corticocancellous bone chips) material.
Indications for Use:	The ANATOMIC PEEK™ PTC Cervical Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The ANATOMIC PEEK™ PTC Cervical Fusion System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach from the C2-C3 disc space to the C7-T1 disc space using autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The ANATOMIC PEEK™ PTC Cervical Fusion System is to be used with supplemental fixation.

	Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral cage.
Comparison of Technological Characteristics with the Predicate Devices	Cervical interbody fusion to provide correction and stabilization during intervertebral body fusion procedures is the technological principle for both the subject and predicate devices. The subject device is manufactured from the same materials noted in the previously cleared referenced devices. Both the subject and predicate devices operate on the usage of PEEK cages inserted into the disc space along with graft material to facilitate fusion at single or multiple levels in the cervical spine. Both the subject and predicate devices are surgically implanted via an anterior approach for the same patient population. Both the subject and predicate interbody devices are required to be used with supplemental fixation.
Performance Data	Clinical data in the form of a comprehensive literature review was provided in support of substantial equivalence of the subject device.
Conclusion	Based on the provided performance data, the subject device is substantially equivalent to the referenced predicate devices.