April 21, 2026

Medtronic Sofamor Danek USA, Inc.
Kelly McDonnell
Sr. Pr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K260216
Trade/Device Name: CD Horizon™ ModuLeX™ Fenestrated Screw Set; CD Horizon™ ModuLeX™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ, PML
Dated: January 23, 2026
Received: January 23, 2026

Dear Kelly McDonnell:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP) titled “PCCP–Small Stature Version 4”. Under section 515C(b)(1) of the Act, a

new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

COLIN O'NEILL -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260216 ?

Please provide the device trade name(s). ?

CD Horizon™ ModuLeX™ Fenestrated Screw Set
CD Horizon™ ModuLeX™ Spinal System

Please provide your Indications for Use below. ?

CD Horizon Fenestrated Screw Set
When used without cement, CD Horizon™ Fenestrated Screws including those with or without Titan nanoLOCK™ Surface Technology with micro- and nano-roughened surface textured features (with or without Sextant™ or Longitude™ instrumentation) are intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (DDD- defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, tumor and/or trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), and/or pseudarthrosis.
Additionally, CD Horizon™ Fenestrated Screws may be used for immobilization and stabilization when used for trauma (e.g. fracture or dislocation) with the usage of bone graft material left to the surgeon's discretion.
When used in conjunction with Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement, CD Horizon™ Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic, lumbar, or sacral spine in whom life expectancy is of insufficient duration to permit achievement of fusion.
CD Horizon™ Fenestrated Screws augmented with Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

CD Horizon Spinal System
The CD Horizon™ Spinal System implants including those with or without Titan nanoLOCK™ Surface Technology with micro- and nano-roughened surface textured features (with or without Sextant™ instrumentation) is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (DDD - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), tumor, and/or pseudarthrosis. Except for hooks, when used as an anterolateral thoracic/lumbar system, CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants may also be used for the same indications as an adjunct to fusion.
With the exception of DDD, CD Horizon™ Legacy™ 3.5mm rods and associated components may be used for the indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.
When used for posterior non-cervical pedicle screw fixation in pediatric patients, CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon™ Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/ spondylolysis, fracture caused by tumor and/or trauma, and/or pseudarthrosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
The CD Horizon™ PEEK rods are intended to provide posterior supplemental fixation when used with an interbody fusion cage for patients diagnosed with DDD. These DDD patients may also have up to Grade 1

spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. The device is intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.
The CD Horizon™ Spire™ plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD (as previously defined), spondylolisthesis, trauma, and/or tumor. To achieve additional levels of fixation, CD Horizon™ Spinal System rods may be connected to the Vertex™ Reconstruction System with the Vertex™ rod connector. Refer to the Vertex™ Reconstruction System package insert for a list of the Vertex™ indications.
The CD Horizon™ LigaMAS Head Assembly used with the LigaPASS™ Spinal 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:
• Spinal trauma, used in sublaminar, or facet wiring techniques
• Spinal reconstruction surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, and kyphosis;
• Spinal degenerative surgery, as an adjunct to spinal fusions.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) Summary
MEDTRONIC Sofamor Danek USA, Inc.

I. Submitter

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132

Contact: Kelly McDonnell
Sr. Principal Regulatory Affairs Specialist
Email: kelly.m.mcdonnell@medtronic.com

Date Prepared: January 23, 2026

II. Subject Device

Name of Device: CD Horizon™ ModuLeX™ Fenestrated Screw Set
CD Horizon™ ModuLeX™ Spinal System

Product Codes: NKB, KWP, KWQ

Common name: Thoracolumbosacral Pedicle Screw System, Spinal Fixation Orthosis, Spinal Fixation Appliance

Classification Name: Thoracolumbosacral Pedicle Screw System (21 CFR 888.3070)
Appliance, Fixation, Spinal Interlaminal (21 CFR 888.3050)
Appliance, Fixation, Spinal Intervertebral Body (21 CFR 888.3060)

Classification: Class II

III. Predicate Devices:

Primary Predicate: CD Horizon™ Fenestrated Screw Set
K232141 (S.E. 08/16/2023)
Additional Predicate 1: CD Horizon™ Spinal System
K223494 (S.E. 05/25/2022)
Additional Predicate 2: CD Horizon™ Spinal System
K221244 (S.E. 01/23/2023)
Additional Predicate 3: CD Horizon™ Spinal System
K233951 (S.E. 03/27/2024)

The predicate devices were not subjected to any Recall.

IV. Description

CD Horizon™ Fenestrated Screw Set
The CD Horizon™ Fenestrated Screw Set consists of a variety of cannulated screws. These screws contain a series of fenestrations which allows polymethylmethacrylate (PMMA) bone cement (Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement) to be injected into the treated site. This cement is used to augment screw fixation into the pedicle in patients whose life expectancy is of insufficient duration to permit achievement of fusion. Implants may incorporate Titan Surface Technologies™, where surfaces include nanoLOCK™ surface treatment designed to improve bone fixation to adjacent bone. nanoLOCK™ surface technology provides a microscopic roughened surface with nano-scale features. nanoLOCK surface technology is specifically engineered to have nano textured features at a nanometer (10^{-9}) level, which has

demonstrated the ability to elicit an endogenous cellular and biochemical response attributed to these nanotextured features *in vitro*. nanoLOCK surface technology demonstrates elements to be considered nanotechnology as outlined in the FDA nanotechnology guidance document.
These implants may also serve as traditional pedicle screws when used without bone cement in patients.
CD Horizon™ Fenestrated Screws are specifically designed to connect to appropriate rods and associated connecting components contained within the CD Horizon™ Spinal System. Refer to the CD Horizon™ Spinal System package insert for information regarding those implants. Care should be taken so the correct components are used in the spinal construct.
CD Horizon™ Fenestrated Screw Set implant components are fabricated from medical grade titanium and/or medical grade titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy. Never use stainless steel and titanium implant components in the same construct.
To achieve best results, do not use CD Horizon™ Fenestrated Screw implants with components from any system other than the CD Horizon™ Spinal System.

CD Horizon™ Spinal System
The CD Horizon™ Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, Crosslink™ Plates, staples, and connecting components, as well as implant components from other Medtronic spinal systems which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. Implants may incorporate Titan Surface Technologies™, where surfaces include nanoLOCK™ surface treatment designed to improve bone fixation to adjacent bone. nanoLOCK™ surface technology provides a microscopic roughened surface with nano-scale features. nanoLOCK surface technology is specifically engineered to have nano textured features at a nanometer (10^{-9}) level, which has demonstrated the ability to elicit an endogenous cellular and biochemical response attributed to these nanotextured features *in vitro*. nanoLOCK surface technology demonstrates elements to be considered nanotechnology as outlined in the FDA nanotechnology guidance document.
A subset of CD Horizon™ Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging in diameter from 3.5mm to 6.35mm), hooks, screws, Crosslink™ plates, and connecting components. Similar to the CD Horizon™ implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.
Certain components within the CD Horizon™ Spinal System are specifically excluded for use in pediatric patients. These include PEEK rods and Spire™ plates. Screws used in pediatric cases are only cleared for use via a posterior approach. All components used in pediatric cases are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, and medical grade cobalt-chromium-molybdenum alloy.
Certain implant components from other Medtronic spinal systems can be used with the CD Horizon™ Spinal System in non-pediatric cases. These components include TSRH™ rods, hooks, screws, plates; Crosslink™ plates, connectors, staples, and washers; GDLH™ rods, hooks, and connectors;

Crosslink™ bar and connectors and Medtronic multi-axial rods and screws. Note that certain components are specifically designed to connect to specific rod diameters, while other components can connect to multiple rod diameters. Care should be taken so the correct components are used in the spinal construct.

CD Horizon™ hooks are intended for posterior use only. CD Horizon™ staples and associated screws are intended for anterior use only. However, for patients of smaller stature and pediatric patients, CD Horizon™ 4.5mm rods and associated components may be used posteriorly.

CD Horizon™ Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEK Optima-LT1. Certain CD Horizon™ Spinal System components may be coated with hydroxyapatite. No warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Never use stainless steel and titanium implant components in the same construct.

Medical grade titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct. PEEK Optima-LT1 implants may be used with titanium or cobalt-chromium-molybdenum alloy implants. CD Horizon™ PEEK
rods are not to be used in pediatric patients. PEEK rods are only to be used with the associated pedicle screws as well as interbody fusion devices in the anterior spinal column.

To achieve best results, do not use CD Horizon™ Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document.

V. Indications for use

CD Horizon™ Fenestrated Screw Set

When used without cement, CD Horizon™ Fenestrated Screws including those with or without Titan nanoLOCK™ Surface Technology with micro- and nano-roughened surface textured features (with or without Sextant™ or Longitude™ instrumentation) are intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (DDD- defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, tumor and/or trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), and/or pseudarthrosis.

Additionally, CD Horizon™ Fenestrated Screws may be used for immobilization and stabilization when used for trauma (e.g. fracture or dislocation) with the usage of bone graft material left to the surgeon's discretion.

When used in conjunction with Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement, CD Horizon™ Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors

involving the thoracic, lumbar, or sacral spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CD Horizon™ Fenestrated Screws augmented with Medtronic HV-R™ Fenestrated Screw Cement or Kyphon™ Xpede™ Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

CD Horizon™ Spinal System

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Except for hooks, when used as an anterolateral thoracic/lumbar system, CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants may also be used for the same indications as an adjunct to fusion. With the exception of DDD, CD Horizon™ Legacy™ 3.5mm rods and associated components may be used for the indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon™ Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/ spondylolysis, fracture caused by tumor and/or trauma, and/or pseudarthrosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD Horizon™ PEEK rods are intended to provide posterior supplemental fixation when used with an interbody fusion cage for patients diagnosed with DDD. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. The device is intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

The CD Horizon™ Spire™ plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD (as previously defined), spondylolisthesis, trauma, and/or tumor.

To achieve additional levels of fixation, CD Horizon™ Spinal System rods may be connected to the Vertex™ Reconstruction System with the Vertex™ rod connector. Refer to the Vertex™ Reconstruction System package insert for a list of the Vertex™ indications.

The CD Horizon™ LigaMAS Head Assembly used with the LigaPASS™ Spinal 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:

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

VI. Comparison of Technological Characteristics with the Predicate Devices

The subject CD Horizon™ ModuLeX™ FNS Screw Set fenestrated screw shanks and CD Horizon™ ModuLeX™ Spinal System screw shanks including those with nanoLOCK™ Surface Technology are spinal fixation implants that have the same indications, intended use, fundamental scientific technology, materials, sterilization method, and similar design as the previously FDA cleared predicates. The main technological difference between the subject screws and the primary predicate devices is the expanded size offering and addition of the nanoLOCK™ Surface Technology to the fenestrated screws.

VII. Performance Data

Mechanical Testing:

In accordance with, "Guidance for Industry and FDA Staff – Spinal System 510(k)'s", Medtronic evaluated the subject implants in comparison to the predicate devices tested per ASTM F1798 (static and dynamic flexion-extension) and ASTM F1717 (static and dynamic compression bending and static torsion). The proposed devices meet the same acceptance criteria as the predicate devices. Therefore, mechanical stability of the subject devices has been deemed equivalent to the predicate devices.

VIII. Conclusion

Based on the supporting information provided in this pre-market notification, the subject fenestrated screw implants are substantially equivalent to the following predicates:

- Primary Predicate: CD Horizon™ Fenestrated Screw Set K232141 (S.E. 08/16/2023)
- Additional Predicate 1: CD Horizon™ Spinal System K223494 (S.E. 05/25/2022)
- Additional Predicate 2: CD Horizon™ Spinal System K221244 (S.E. 01/23/2023)
- Additional Predicate 3: CD Horizon™ Spinal System K233951 (S.E. 03/27/2024)

IX. Predetermined Change Control Plan

This submission includes a predetermined change control plan (PCCP) to expand sizing of CD Horizon™ Spinal System devices for dimensional design changes only via line extension updates. The PCCP establishes a comprehensive framework for managing pre-planned modifications. It details the methods for evaluating these modifications while ensuring the CD Horizon™ Spinal System devices remain as safe and effective as the predicate devices. Testing will include the following:

- Static compression bending, dynamic compression bending, and static torsion per ASTM F1717

- Static flexion-extension, dynamic flexion-extension, axial gripping capacity, torsional gripping capacity, and neutral and maximum angle dissociation testing per ASTM F1798
- Navigated instruments accuracy analysis
- Navigated instruments simulated use

Line extension updates will be communicated by updating labeling in accordance with the authorized PCCP to provide users with current information regarding the new system components.