



May 7, 2026

Globus Medical, Inc.  
Jennifer Antonacci  
Director, Regulatory Affairs  
2560 General Armistead Ave.  
Audubon, Pennsylvania 19403

Re: K253739

Trade/Device Name: SCRIPT™ Rods, CREO™ Stabilization System, REVERE® Stabilization System, REVERE® 4.5 Stabilization System, NuVasive Reline™ System

Regulation Number: 21 CFR 888.3070

Regulation Name: Thoracolumbosacral Pedicle Screw System

Regulatory Class: Class II

Product Code: NKB, KWP, OSH, PGM

Dated: April 7, 2026

Received: April 8, 2026

Dear Jennifer Antonacci:

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.

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](mailto: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.

K253739

?

Please provide the device trade name(s).

?

SCRIPT™ Rods, CREO™ Stabilization System, REVERE® Stabilization System, REVERE® 4.5 Stabilization System, NuVasive Reline™ System

Please provide your Indications for Use below.

?

CREO™ Stabilization System:

The CREO™ Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients. These devices are indicated as an adjunct to fusion for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO™ Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO™ Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO™ Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO™ Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation, the CREO™ Stabilization System rods may be connected to the REVERE™ Stabilization System (4.5mm, 5.5mm, or 6.35mm rod) or ELLIPSE™ Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. Refer to the REVERE™, or ELLIPSE™ system package insert for instructions and indications of use.

In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

Globus Navigation instruments are intended to be used during the preparation and placement of CREO screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

When used for posterior fixation in conjunction with FORTRESS™ or FORTRESS-Plus™ bone cement, the

CREO™ Fenestrated Screw System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CREO™ Fenestrated screws augmented with FORTRESS™ and FORTRESS-Plus™ bone cements are for use at spinal levels where the structural integrity of the spine is not severely compromised.

#### REVERE® Stabilization System

The REVERE® Stabilization System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the REVERE® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as a posterior non-pedicle screw fixation system, the REVERE® Stabilization System is intended for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's disease), fracture, pseudoarthrosis, tumor resection, and/or failed previous fusion. Overall levels of fixation are T1-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the REVERE® Stabilization System is intended for anterolateral screw (with or without staples or staple plates) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

Globus Navigation Instruments are intended to be used during the preparation and placement of REVERE® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

#### REVERE® 4.5 Stabilization System

The REVERE® 4.5 Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/iliac), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and pediatric patients. These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by

history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis).

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the REVERE® 4.5 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The REVERE® 4.5 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the REVERE® 4.5 Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. Refer to the REVERE® or ELLIPSE® system package insert for instructions and indications of use.

In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

#### NuVasive® Reline® System:

When used as a pedicle screw fixation system in skeletally mature patients, the NuVasive Reline System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment
3. Fracture
4. Dislocation
5. Scoliosis
6. Kyphosis
7. Spinal tumor and/or
8. Failed previous fusion (pseudoarthrosis)

The NuVasive Reline System is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic and lumbar spine, the NuVasive Reline System is also intended for the following indications:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
2. Spinal stenosis,
3. Spondylolisthesis,
4. Spinal deformities,
5. Fracture,
6. Pseudoarthrosis
7. Tumor resection and/or
8. Failed previous fusion

When used for posterior non-cervical screw fixation in pediatric patients, NuVasive Reline System is

indicated as an adjunct to fusion to treat:

1. Adolescent idiopathic scoliosis
2. Progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including infantile and juvenile idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis
3. Spondylolisthesis
4. Spondylolysis
5. Pseudarthrosis
6. Failed prior fusion and
7. Fracture caused by tumor and/or trauma in pediatric patients

Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

In order to achieve additional levels of fixation, the Reline System rods may be connected to the Armada System.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)  
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?

**510(k) Summary: SCRIPT™ Rods, CREO™ Stabilization System, REVERE® Stabilization System, REVERE® 4.5 Stabilization System, NuVasive Reline™ System**

**Company:** Globus Medical Inc.  
2560 General Armistead Ave.  
Audubon, PA 19403  
610-930-1800

**Contact:** Jennifer Antonacci, Ph.D.  
Director, Regulatory Affairs

**Secondary Contact:** Suganya Gopalakrishnan  
Regulatory Specialist

**Date Prepared:** November 24, 2025

**Device Name:** SCRIPT™ Rods  
CREO™ Stabilization System  
REVERE® Stabilization System  
REVERE® 4.5 Stabilization System  
NuVasive Reline™ System

**Common Name:** Spinal Rods

**Classification:** Per 21 CFR as follows:  
§888.3070 Thoracolumbosacral pedicle screw system  
§888.3050 Spinal Interlaminar Fixation Orthosis  
§888.3060 Spinal Intervertebral Body Fixation Orthosis  
Product Code(s): NKB, KWP, OSH, PGM  
Regulatory Class: II, Panel Code: 87

**Primary Predicate:** CREO™ Stabilization System (K124058)

**Other Predicates:** CREO™ Stabilization System (K143633, K203153)  
REVERE® Stabilization System (K061202, K133350, K181068)  
REVERE® 4.5 Stabilization System (K113395, K181068)  
NuVasive Reline™ System (K132014, K223181)  
Medtronic Pass LP Spinal System (K140738, K220724)

**Purpose:**

The purpose of this submission is to request clearance for the SCRIPT™ Rods, for use with previously cleared CREO™, REVERE®, REVERE® 4.5, and Reline™ implants.

**Device Description:**

SCRIPT™ Rods consist of spinal rods in a variety of diameters and lengths. The rods are patient-matched to accommodate the curvature of the patient's spine. SCRIPT™ rods mate with previously cleared CREO™ Stabilization System, REVERE® and REVERE® 4.5 Stabilization Systems, and NuVasive Reline™ System implants which consist of a variety of rods, screws, hooks, staples, locking caps, and connectors. SCRIPT™ Rods can be rigidly locked into a variety of configurations with CREO™, REVERE® and Reline™ components for the individual patient and surgical condition. Rods may be used anteriorly or posteriorly. SCRIPT™ Rods are manufactured from titanium alloy, commercially pure titanium, stainless steel, or cobalt chromium-molybdenum alloy.

**Indications for Use:****CREO™ Stabilization System**

The CREO™ Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients. These devices are indicated as an adjunct to fusion for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO™ Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO™ Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO™ Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO™ Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation, the CREO™ Stabilization System rods may be connected to the REVERE™ Stabilization System (4.5mm, 5.5mm, or 6.35mm rod) or ELLIPSE™ Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. Refer to the REVERE™, or ELLIPSE™ system package insert for instructions and indications of use.

In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

Globus Navigation Instruments are intended to be used during the preparation and placement of CREO® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

When used for posterior fixation in conjunction with FORTRESS™ or FORTRESS-Plus™ bone cement, the CREO™ Fenestrated Screw System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CREO™ Fenestrated screws augmented with FORTRESS™ and FORTRESS-Plus™ bone cements are for use at spinal levels where the structural integrity of the spine is not severely compromised.

### **REVERE® Stabilization System**

The REVERE® Stabilization System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the REVERE® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as a posterior non-pedicle screw fixation system, the REVERE® Stabilization System is intended for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history

and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's disease), fracture, pseudoarthrosis, tumor resection, and/or failed previous fusion. Overall levels of fixation are T1-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the REVERE® Stabilization System is intended for anterolateral screw (with or without staples or staple plates) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

Globus Navigation Instruments are intended to be used during the preparation and placement of REVERE® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

#### **REVERE® 4.5 Stabilization System**

The REVERE® 4.5 Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and pediatric patients. These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis).

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the REVERE® 4.5 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The REVERE® 4.5 Stabilization

System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the REVERE® 4.5 Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. Refer to the REVERE® or ELLIPSE® system package insert for instructions and indications of use.

In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

### **NuVasive® Reline® System**

When used as a pedicle screw fixation system in skeletally mature patients, the NuVasive Reline System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment
3. Fracture
4. Dislocation
5. Scoliosis
6. Kyphosis
7. Spinal tumor and/or
8. Failed previous fusion (pseudoarthrosis)

The NuVasive Reline System is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic and lumbar spine, the NuVasive Reline System is also intended for the following indications:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
2. Spinal stenosis,
3. Spondylolisthesis,

4. Spinal deformities,
5. Fracture,
6. Pseudoarthrosis
7. Tumor resection and/or
8. Failed previous fusion

When used for posterior non-cervical screw fixation in pediatric patients, NuVasive Reline System is indicated as an adjunct to fusion to treat:

1. Adolescent idiopathic scoliosis
2. Progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including infantile and juvenile idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis
3. Spondylolisthesis
4. Spondylolysis
5. Pseudarthrosis
6. Failed prior fusion and
7. Fracture caused by tumor and/or trauma in pediatric patients

Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

In order to achieve additional levels of fixation, the Reline System rods may be connected to the Armada System.

**Performance Testing:**

Verification and validation testing were conducted to confirm that the SCRIPT™ Rods meet performance requirements. The following testing was conducted:

- Cadaveric Usability testing under clinically relevant scenarios. This testing demonstrated that:
  - SCRIPT™ Rods as planned and manufactured met the requirements for bending, and were designed per the plan
- Non-clinical system and software verification and validation - demonstrated compliance with user needs and corresponding design inputs

**Technological Characteristics:**

Subject implants have the same or similar technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

**Basis of Substantial Equivalence:**

Subject devices have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject devices to the predicate devices.