November 19, 2019

Medos International SARL
% Mr. Sergio M. Cordeiro
Senior Regulatory Affairs Specialist
DePuy Synthes Spine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K192281
Trade/Device Name: AEGIS® Anterior Lumbar Plate System, ALC Dynamized Fixation System, Anterior ISOLA® Spine System, BOWTI® Anterior Buttress Staple Spinal System, DISCOVERY® Screw System, EXPEDIUM® Anterior Spine System, FRONTIER® Anterior Scoliosis System, KANEDA™ Anterior Scoliosis System, KANEDA™ SR Anterior Spinal System, M-2® Anterior Plate System, MOUNTAINEER® Laminoplasty System, PROFILE™ Anterior Thoracolumbar Plate System, UNIVERSITY PLATE® Anterior System, VIPER® F2 Facet Fixation System
Regulatory Class: Unclassified
Product Code: MRW, NKB, NQW, KWQ
Dated: August 21, 2019
Received: August 22, 2019

Dear Mr. Cordeiro:

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. 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 located 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.

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

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 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,

Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192281

Device Name
AEGIS® Anterior Lumbar Plate System

Indications for Use *(Describe)*

The AEGIS Anterior Lumbar Plate System is intended for use as an anteriorly placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The device is intended as a temporary fixation device until fusion is achieved. The AEGIS Anterior Lumbar Plate System is intended for anterior lumbar (L1-S1) fixation for the following indications are:

• 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);
• deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
• tumor;
• pseudarthrosis; and
• previous failed fusion.

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)

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Device Name

ALC Dynamized Fixation System

Indications for Use *(Describe)*

The Anterior Dynamized system is intended for use in anterior decompression instrumentation and fusion for kyphotic deformities, post traumatic kyphotic deformities, degenerative disc disease (defined as discogenic and back pain with degeneration of the disc confirmed by history and radiographic studies), burst fractures, tumors and previous failed surgery of the spine. The intended levels for treatment range from T10 to L3.

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)

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Device Name
Anterior ISOLA® Spine System

Indications for Use *(Describe)*

The ISOLA Spine System when used as anterior thoracic/lumbar screw fixation system, is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

Type of Use *(Select one or both, as applicable)*

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Device Name

BOWTI® Anterior Buttress Staple Spinal System

Indications for Use *(Describe)*

The BOWTI Anterior Buttress Staple System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

The BOWTI Anterior Buttress Staple System is intended for anterior intravertebral body screw fixation/attachment to the T1-S1 spine over one vertebral body extending into the adjacent intervertebral space. Specifically, the device is intended for stabilization and buttressing of bone graft as an aid to spinal fusion. It may be used with other anterior, anterolateral or posterior spinal systems.

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)

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Device Name
DISCOVERY® Screw System

Indications for Use *(Describe)*

The DISCOVERY Facet Screw Fixation System is intended to stabilize the spine as an aid to fusion by two different fixation methods:

Transfacet fixation: The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle.

Translaminar Facet fixation: The screws are inserted bilaterally through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet across the facet joint and into the inferior pedicle.

For both methods this system is indicated for the posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels:

1) Trauma, including spinal fractures and/or dislocations;
2) Spondylolisthesis;
3) Spondylolysis;
4) Pseudoarthrosis or failed previous fusions which are symptomatic, or which may cause secondary instability or deformity;
5) Degenerative diseases which include:
(a) degenerative disc disease (ddd) as defined by back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or
(b) degenerative disease of the facets with instability.

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)

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Device Name

EXPEDIUM® Anterior Spine System

Indications for Use *(Describe)*

The EXPEDIUM Anterior Spine System is intended for anterolateral screw fixation of the T4 to L4 levels of the spine, with metal at least 1 cm from a major vessel. The EXPEDIUM Anterior Spine System may be used in either thoracoscopic procedures or open procedures.

The EXPEDIUM Anterior Spine System is indicated for:
• 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;
• deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
• tumor;
• pseudarthrosis; and previous failed fusion.

Type of Use *(Select one or both, as applicable)*

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510(k) Number *(if known)*
K192281

Device Name
FRONTIER® Anterior Scoliosis System

Indications for Use *(Describe)*

The FRONTIER Anterior Scoliosis System is intended for anterolateral screw fixation to the T4 to L4 levels of the spine, with metal at least 1cm from a major vessel. The FRONTIER Anterior Scoliosis System may be used in either thoracoscopic procedures or open procedures.

The FRONTIER Anterior Scoliosis System is indicated for:
• 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;
• deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
• tumor;
• pseudarthrosis; and previous failed fusion.

Type of Use *(Select one or both, as applicable)*

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510(k) Number *(if known)*

K192281

Device Name

KANEDA™ Anterior Scoliosis System

Indications for Use *(Describe)*

The KANEDA Anterior Scoliosis System is intended for anterolateral screw fixation to the T4 to L4 levels of the spine.

The KANEDA Anterior Scoliosis System is indicated for:
• 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;
• deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
• tumor;
• pseudarthrosis; and previous failed fusion.

Type of Use *(Select one or both, as applicable)*

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K192281

Device Name

KANEDA™ SR Anterior Spinal System

Indications for Use *(Describe)*

The KANEDA SR Anterior Spinal System is intended for anterolateral screw fixation to the T10 to L3 levels of the spine. Specific indications are degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, kyphosis, lordosis), tumor, fracture and revision of previous surgery.

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)

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Device Name
M-2® Anterior Plate System

Indications for Use *(Describe)*

The intended levels for treatment with the M-2 Anterior Plate System are from T3 to L3. In order to treat levels from T3 to L3, plate attachment is from T2 to L4. The M-2 Anterior Plate System is intended to treat one motion segment per construct.

The M-2 Anterior Plate System is indicated for:
• 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;
• deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
• tumor;
• pseudarthrosis; and previous failed fusion.

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)

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Device Name

MOUNTAINEER® Laminoplasty System

Indications for Use *(Describe)*

The MOUNTAINEER Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The MOUNTAINEER Laminoplasty System is used to hold or buttress the allograft or autograft material in place in order to prevent the allograft or autograft material from expulsion or impinging the spinal cord.

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)

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Device Name

PROFILE™ Anterior Thoracolumbar Plate System

Indications for Use *(Describe)*

The intended levels for treatment with the PROFILE Anterior Thoracolumbar Plate System are from T1-L5 spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

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)

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Device Name
UNIVERSITY PLATE® Anterior System

Indications for Use *(Describe)*

The UNIVERSITY PLATE Anterior System is intended for lateral screw fixation to the T9-L4 levels of the spine, and is not suitable for the attachment to the sacrum. Specific indications are fracture, tumor, previous failed fusion and pseudarthrosis, and degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).

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)

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Device Name
VIPER® F2 Facet Fixation System

Indications for Use *(Describe)*

The VIPER F2 Facet Fixation System is intended to stabilize the spine as an aid to fusion by the transfacet fixation method only:

Transfacet fixation: The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle.

This system is indicated for the posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels:

1) Trauma, including spinal fractures and/or dislocations;
2) Spondylolisthesis;
3) Spondylolysis;
4) Pseudoarthrosis or failed previous fusions which are symptomatic, or which may cause secondary instability or deformity;
5) Degenerative diseases which include:
(a) degenerative disc disease (ddd) as defined by back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or
(b) degenerative disease of the facets with instability.

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)

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510(k) SUMMARY

A. Submitter Information

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B. Date Prepared

August 21, 2019

C. Device Name

Trade/Proprietary Names:

AEGIS® Anterior Lumbar Plate System
ALC Dynamized Fixation System
Anterior ISOLA® Spine System
BOWTI® Anterior Buttress Staple Spinal System
DISCOVERY® Screw System
EXPEDIUM® Anterior Spine System
FRONTIER® Anterior Scoliosis System
KANEDA™ Anterior Scoliosis System
KANEDA™ SR Anterior Spinal System
M-2® Anterior Plate System
MOUNTAINEER® Laminoplasty System
PROFILE™ Anterior Thoracolumbar Plate System
UNIVERSITY PLATE® Anterior System
VIPER® F2 Facet Fixation System

Common/Usual Names: Orthosis, Anterior Spinal Fixation Devices

Classification Names: KWQ – Class II – 21 CFR §888.3060
Spinal intervertebral body fixation orthosis

NQW – Class II – 21 CFR §888.3050
Spinal interlaminal fixation orthosis

NKB – Class II – 21 CFR §888.3070
Thoracolumbosacral pedicle screw system

MRW – Unclassified – Pre-Amendment

D. Predicate Device Names

Primary Predicate: EXPEDIUM® Anterior Spine System
(K131802)

Additional Predicates: AEGIS® Anterior Lumbar Plate System
(K052546)

ALC Dynamized Fixation System
(K953978)

Anterior ISOLA® Spine System
(K943819, K980485, K944756)

BOWTI® Anterior Buttress Staple Spinal System
(K021039)

DISCOVERY® Screw System
(K012773, K903810)

FRONTIER® Anterior Scoliosis System
(K012916)

KANEDA™ Anterior Scoliosis System
(K873826, K974757)

KANEDA™ SR Anterior Spinal System
(K971248)

M-2® Anterior Plate System
(K972718)

MOUNTAINEER® Laminoplasty System
(K091994)

PROFILE™ Anterior Thoracolumbar Plate System
(K973060)

UNIVERSITY PLATE® Anterior System
(K980228)

VIPER® F2 Facet Fixation System
(K101762)

E. Submission Purpose

Obtain clearance for magnetic resonance compatibility labeling of the systems listed.

F. Device Descriptions

AEGIS® Anterior Lumbar Plate System
The AEGIS Anterior Plate System consists of an assortment of titanium alloy plates and screws. The plates are uniquely shaped to conform to the anatomy of the anterior spine. They feature screw holes for final fixation to the vertebral bodies.

ALC Dynamized Fixation System
The ALC Dynamized Fixation System is a construct consisting of implant grade titanium alloy dynamized closed screws, closed transverse fixator connector, anterior rods and a closed blocker. The ALC Dynamized Fixation System construct allows continual compression of the bone graft while avoiding hyperextension type forces on the construct.

Anterior ISOLA® Spine System
The Anterior ISOLA Spine System consists of spinal rods, open and closed screws, washers, caps, set screws, and staples.

BOWTI® Anterior Buttress Staple Spinal System
The BOWTI Anterior Buttress Staple System consists of staples and screws. The staple is uniquely shaped to conform to the anatomy of the anterior spine. It features two prongs, which engage the vertebral body and prevent rotation, and a screw slot for final fixation.

DISCOVERY® Screw System
The DISCOVERY Facet Screw Fixation System consists of titanium alloy bone screws and washers designed to transfix the facet articular process in the spine to enhance spinal fusion and stability. The self-tapping screws are available in two configurations: fully threaded and partially threaded.

EXPEDIUM® Anterior Spine System
The EXPEDIUM Anterior Spine System consists of spinal rods, monoaxial screws, staples, washers, and cross connectors. The components of the EXPEDIUM Anterior Spine System are designed with anatomic limitations in mind, therefore minimizing the profile of the construct.

FRONTIER® Anterior Scoliosis System
The FRONTIER Anterior Scoliosis System is a construct that consists of spinal staples, semi-blunt tip open screws, washers, and 3/16 inch (4.75mm) diameter spinal rods.

KANEDA™ Anterior Scoliosis System
The KANEDA Anterior Scoliosis System is a construct that consists of Kass spinal staples, Kass blunt tip open and closed screws, standard Isola open and closed screws and Isola 3/16 inch (4.75mm) diameter spinal rods.

KANEDA™ SR Anterior Spinal System
The KANEDA SR Anterior Spinal System is an anterolateral spinal implant system which is used in conjunction with some components of the Isola Spine System. KANEDA SR consists of longitudinal members, spinal anchors and transverse rod couplers. The longitudinal members are 1/4 inch (6.35 mm) diameter smooth spinal rods. The Isola rods can be cut to size during the surgical procedure or Kaneda rods are available in precut lengths. The contoured spiked plates are designed to help the construct anchors resist axial forces and serve as a guide for placement of the screws. The plates are available in three sizes (small, medium and large) and are designed as pairs with specific caudal and rostral components. The screws serve to anchor the vertebral bodies to the longitudinal rods and are available in open and closed screw formats. Caps are available to capture the rod onto the open screws. Set screws are used to tighten the screws to the rods. The transverse couplers add stability, contributing to the construct's ability to resist torsional loads.

M-2® Anterior Plate System
The M-2 Anterior Plate System is a construct which consists of one plate attached to the lateral aspect of the vertebrae by either four screws or two screws/two bolts. The components of the M-2 Anterior Plate System have been designed with anatomic limitations in mind.

MOUNTAINEER® Laminoplasty System
The MOUNTAINEER Laminoplasty System is an implant system that consists of various sizes of plates and screws. The plates are available in the Inline, Inline Side-By-Side, and Offset Side-By-Side configurations. The proposed plate devices come in a preformed shape with holes for bone screws. The plates also contain a slot in the middle portion of the plate for allograft or autograft material attachment. The allograft or autograft material is secured to the plate using bone screws that are inserted through the middle slot on the top portion of the plate.

PROFILE™ Anterior Thoracolumbar Plate System
The PROFILE Anterior Thoracolumbar Plate System consists of various lengths of thoracolumbar and high thoracic plates, cancellous screws, cancellous bolts with locking nuts and screws and bone graft screws. The anterior thoracolumbar plates are implanted using two cancellous bolts placed through the plate's bolt slots and fixed with locking nuts and screws, two cancellous screws placed through the plate's threaded screw holes, and an optional graft screw which can be placed through the plate's center slot to provide fixation between the plate and a strut graft if desired. The high thoracic plates are implanted using four to six cancellous screws, placed through the plate's screw holes.

UNIVERSITY PLATE® Anterior System
The UNIVERSITY Plate Anterior System plates are fabricated from implant grade titanium alloy. These plates have a contoured low profile to match the curvature of the lateral aspect of the thoracolumbar vertebral bodies. Three pairs of nested slots allow a wide range of screw and bolt placement, while the spherical countersinks allow up to 15 degrees of screw angulation. The UNIVERSITY Plate Anterior System plates are either rectangular or distally tapered, and come in a variety of lengths. Distally tapered plates are used at the L4 level to avoid contact with the common iliac vessels.

VIPER® F2 Facet Fixation System
The VIPER F2 Facet Fixation System consists of titanium alloy bone screws designed to transfix the facet articular process in the spine to enhance spinal fusion and stability. Washers are available to increase the load bearing area of the screw in contact with the bone. These washers are designed to angulate about the head of the bone screws to provide optimal bony contact over a range of screw trajectories.

G. Intended Use

AEGIS® Anterior Lumbar Plate System
The AEGIS Anterior Lumbar Plate System is intended for use as an anteriorly placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The device is intended as a temporary fixation device until fusion is achieved. The AEGIS Anterior Lumbar Plate System is intended for anterior lumbar (L1-S1) fixation for the following indications are:

- 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);
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- pseudarthrosis; and
- previous failed fusion.

ALC Dynamized Fixation System
The Anterior Dynamized system is intended for use in anterior decompression instrumentation and fusion for kyphotic deformities, post traumatic kyphotic deformities, degenerative disc disease (defined as discogenic and back pain with degeneration of the disc confirmed by history and radiographic studies), burst fractures, tumors and previous failed surgery of the spine. The intended levels for treatment range from T10 to L3.

Anterior ISOLA® Spine System
The ISOLA Spine System when used as anterior thoracic/lumbar screw fixation system, is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

BOWTI® Anterior Buttress Staple Spinal System
The BOWTI Anterior Buttress Staple System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

The BOWTI Anterior Buttress Staple System is intended for anterior intravertebral body screw fixation/attachment to the T1-S1 spine over one vertebral body extending into the adjacent intervertebral space. Specifically, the device is intended for stabilization and buttressing of bone graft as an aid to spinal fusion. It may be used with other anterior, anterolateral or posterior spinal systems.

DISCOVERY® Screw System
The DISCOVERY Facet Screw Fixation System is intended to stabilize the spine as an aid to fusion by two different fixation methods:

<u>Transfacet fixation</u>: The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle.

<u>Translaminar Facet fixation</u>: The screws are inserted bilaterally through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet across the facet joint and into the inferior pedicle.

For both methods this system is indicated for the posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels:

1) Trauma, including spinal fractures and/or dislocations;
2) Spondylolisthesis;
3) Spondylolysis;
4) Pseudoarthrosis or failed previous fusions which are symptomatic, or which may cause secondary instability or deformity;
5) Degenerative diseases which include:

(a) degenerative disc disease (ddd) as defined by back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or
(b) degenerative disease of the facets with instability.

EXPEDIUM® Anterior Spine System
The EXPEDIUM Anterior Spine System is intended for anterolateral screw fixation of the T4 to L4 levels of the spine, with metal at least 1 cm from a major vessel. The EXPEDIUM Anterior Spine System may be used in either thoracoscopic procedures or open procedures.

The EXPEDIUM Anterior Spine System is indicated for:

- 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;
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- pseudarthrosis; and previous failed fusion.

FRONTIER® Anterior Scoliosis System
The FRONTIER Anterior Scoliosis System is intended for anterolateral screw fixation to the T4 to L4 levels of the spine, with metal at least 1cm from a major vessel. The FRONTIER Anterior Scoliosis System may be used in either thoracoscopic procedures or open procedures.

The FRONTIER Anterior Scoliosis System is indicated for:

- 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;
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- pseudarthrosis; and previous failed fusion.

KANEDA™ Anterior Scoliosis System
The KANEDA Anterior Scoliosis System is intended for anterolateral screw fixation to the T4 to L4 levels of the spine.

The KANEDA Anterior Scoliosis System is indicated for:

- 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;
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- pseudarthrosis; and previous failed fusion.

KANEDA™ SR Anterior Spinal System
The KANEDA SR Anterior Spinal System is intended for anterolateral screw fixation to the T10 to L3 levels of the spine. Specific indications are degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, kyphosis, lordosis), tumor, fracture and revision of previous surgery.

M-2® Anterior Plate System
The intended levels for treatment with the M-2 Anterior Plate System are from T3 to L3. In order to treat levels from T3 to L3, plate attachment is from T2 to L4. The M-2 Anterior Plate System is intended to treat one motion segment per construct.

The M-2 Anterior Plate System is indicated for:
- 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;
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- pseudarthrosis; and previous failed fusion.

MOUNTAINEER® Laminoplasty System
The MOUNTAINEER Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The MOUNTAINEER Laminoplasty System is used to hold or buttress the allograft or autograft material in place in order to prevent the allograft or autograft material from expulsion or impinging the spinal cord.

PROFILE™ Anterior Thoracolumbar Plate System
The intended levels for treatment with the PROFILE Anterior Thoracolumbar Plate System are from T1-L5 spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

UNIVERSITY PLATE® Anterior System
The UNIVERSITY PLATE Anterior System is intended for lateral screw fixation to the T9-L4 levels of the spine, and is not suitable for the attachment to the sacrum. Specific indications are fracture, tumor, previous failed fusion and pseudarthrosis, and

degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).

VIPER® F2 Facet Fixation System
The VIPER F2 Facet Fixation System is intended to stabilize the spine as an aid to fusion by the transfacet fixation method only:

Transfacet fixation: The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the inferior pedicle.

This system is indicated for the posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels:

1) Trauma, including spinal fractures and/or dislocations;
2) Spondylolisthesis;
3) Spondylolysis;
4) Pseudoarthrosis or failed previous fusions which are symptomatic, or which may cause secondary instability or deformity;
5) Degenerative diseases which include:
   (a) degenerative disc disease (ddd) as defined by back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or
   (b) degenerative disease of the facets with instability.

H. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The subject devices maintain the design characteristics of the predicate devices. Intended use remains consistent with the predicate devices. The subject devices are provided with additional labeling language regarding magnetic resonance (MR) compatibility.

I. Materials

The subject device materials remain identical to the predicate device materials, which consist of Implant Grade Pure Titanium or Titanium Alloy conforming to ASTM F-67, ASTM F-136 or ASTM F-1472 specifications; Stainless Steel conforming to ASTM F-138, ASTM F-134, or F-2229 specifications; Cobalt-Nickel-Chromium-Molybdenum Alloy Wire conforming to ASTM F-562 specifications; and Cobalt-Chromium-Molybdenum Alloy conforming to ASTM F-1537 specifications.

J. Performance Data

Non-clinical testing was conducted in alignment with the following standards:

- ASTM F2213 *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*
- ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*
- ASTM F2119 *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*
- ASTM F2182 *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging*

Results demonstrated compatibility conditions of the subject devices in the MR environment.

K. Conclusion

Evaluation of subject device intended use and technological characteristics demonstrates substantial equivalence with the predicate devices. Performance data supports the addition of magnetic resonance compatibility information to subject device labeling.