February 16, 2021

Aegis Spine
% Meredith Lee May
Director of Consulting
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K210035
Trade/Device Name: ZESPIN SI Joint Fusion System, MegaCerfix Posterior Cervical Fixation System, MegaCerfix Anterior Cervical Plate System, Spinema Lumbar Plate System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, NKG, KWP, KWQ
Dated: December 30, 2020
Received: January 6, 2021

Dear Meredith Lee May:

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,

for

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

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 on last page.

510(k) Number *(if known)*

Device Name
ZESPIN SI Joint Fusion System

Indications for Use *(Describe)*

The ZESPIN SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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 on last page.

510(k) Number *(if known)*

Device Name
MegaCerfix Posterior Cervical Fixation System

Indications for Use *(Describe)*

The MegaCerfix Posterior Cervical Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The MegaCerfix Posterior Cervical Fixation System is also 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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 on last page.

510(k) Number *(if known)*

Device Name
MegaCerfix Anterior Cervical Plate System

Indications for Use *(Describe)*

The MegaCerfix Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudoarthrosis,
- failed previous fusion,
- spinal stenosis.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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 on last page.

510(k) Number *(if known)*

Device Name
Spinema Lumbar Plate System

Indications for Use *(Describe)*

The Spinema Lumbar Plate System is indicated for use via the anterior, lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. This system is indicated in the treatment of lumbar and lumbosacral (L1-S1) 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 patient history and radiographic studies), pseudoarthrosis, spondylolysis, scolosis, spondylolisthesis, lordotic deformities of the spine, 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

5. 510(K) SUMMARY

Submitter's Name:	Aegis Spine
Submitter's Address:	9781 S. Meridian Blvd, Ste 300 Englewood, CO 80112
Submitter's Telephone:	+1.303.741.4123
Contact Person:	Meredith Lee May MS, RAC Empirical Testing Corp. 719.337.7579 MMay@EmpiricalTech.com
Date Summary was Prepared:	30-Dec-2020
Trade or Proprietary Name:	ZESPIN SI Joint Fusion System, MegaCerfix Posterior Cervical Fixation System, MegaCerfix Anterior Cervical Plate System, and Spinema Lumbar Plate System
Common or Usual Name:	sacroiliac joint fixation, posterior cervical screw system, appliance, fixation, spinal interlaminal, and appliance, fixation, spinal intervertebral body
Classification:	Class II per 21 CFR §888.3040, 3075, 3050, & 3060
Product Code:	OUR, NKG, KWP, KWQ
Classification Panel:	Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

ZESPIN SI Joint Fusion System consists of different diameter bone screws in various lengths and thread configurations to accommodate variations in patient anatomy. The devices are manufactured from titanium alloy per ASTM F136.

- Arch Screw will be implanted in patient's bone then autograft will be inserted.
- Locking Screw can be used with washer or can be used on its own
- Self-tapping flute centers screw for easy insertion

The MegaCerfix Posterior Cervical Fixation System is a top-loading, multiple component, posterior (cervical-thoracic) spinal fixation system which consists of polyscrew, Reduction poly screw, partially screw, semi-reduction partially screw, straight rod, curved rod, set screw, hooks and accessories that can be used via an open surgical approach. The devices are manufactured from titanium alloy per ASTM F136 and cobalt chromium per ASTM F1537.

The MegaCerfix Anterior Cervical Plate System is composed of plates, screws and lockers which are made from titanium alloy per ASTM F136. These plates attach to the anterior cervical spine with a minimum of four screws per plate. The plates are offered in one-level, two-level, three-level, four-level fusion configurations (19~97mm). The plate screws are 3.5mm and 4.0mm diameter head screws. They are self-tapping and self-drilling threaded. This device can be provided both as non-sterile and sterile.

The Spinema Lumbar Plate System's implants are Lumbar Plate System intended for use as an aid in spinal fixation. They are made from titanium alloy per ASTM F136. The Spinema Lumbar Plate System consists of a variety of shapes and sizes of plates and screws. The plate has been designed to include spikes for added stability and alignment during screw insertion. The plates feature a curvature for anatomic fit. The diameter of screw is available from 5.5 to 6.0 mm and the length from 20 to 55 mm.

INDICATIONS FOR USE

The *ZESPIN SI Joint Fusion System* is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

The *MegaCerfix Posterior Cervical Fixation System* is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The MegaCerfix Posterior Cervical Fixation System is also 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 cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The *MegaCerfix Anterior Cervical Plate System* is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudoarthrosis,
- failed previous fusion,
- spinal stenosis.

The *Spinema Lumbar Plate System* is indicated for use via the anterior, lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. This system is indicated in the treatment of lumbar and lumbosacral (L1-S1) 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 patient history and radiographic studies), pseudoarthrosis, spondylolysis, scolosis, spondylolisthesis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

TECHNOLOGICAL CHARACTERISTICS

The subject devices are identical to the predicate devices in all characteristics.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K181600	PathLoc-SI Joint Fusion System	L&K BIOMED CO., LTD	Primary
K200793	CastleLoc-S & LnK Posterior Cervical System	L&K BIOMED CO., LTD	Additional
K190425	CastleLoc-P Anterior Cervical Plate System	L&K BIOMED CO., LTD	Additional
K192481	AccelFix Lumbar Plate System	L&K BIOMED CO., LTD	Additional

PERFORMANCE DATA

The ZESPIN SI Joint Fusion System, MegaCerfix Posterior Cervical Fixation System, MegaCerfix Anterior Cervical Plate System, and Spinema Lumbar Plate System are identical to the predicates; mechanical testing is not required to establish substantial equivalence.

CONCLUSION

The overall technology characteristics lead to the conclusion that the ZESPIN SI Joint Fusion System, MegaCerfix Posterior Cervical Fixation System, MegaCerfix Anterior Cervical Plate System, and Spinema Lumbar Plate System is substantially equivalent to the predicate devices.