March 6, 2020

SeohanCare Co., Ltd
℅ Meredith L. May, MS, RAC
Vice President - Empirical Consulting
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K191655
Trade/Device Name: MEGAFIX® Pedicle Screw Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: February 3, 2020
Received: February 5, 2020

Dear Ms. 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,

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)*

K191655

Device Name
MEGAFIX® Pedicle Screw Spinal System

Indications for Use *(Describe)*

The MEGAFIX(R) Pedicle Screw Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion using autograft or allograft. This system is intended for posterior, non-cervical pedicle fixation of the lumbar and sacral spine for 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 (Grade 1 and 2) of the L5-S1; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous 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.

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MEGAFIX® Pedicle Screw Spinal System
Traditional 510(k)

510(k) Summary

This 510(k) Summary is being submitted in according with requirement of 21 CFR Part 807.92.

Submitter's Name	SeohanCare Co., Ltd.
Submitter's Address	2F, Da-dong, 22, Gimpo-Daero 2918 beon-Gil, Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10020 Republic of Korea
Submitter's Telephone number	+82-70-8769-6041
Contact Person	Meredith L. May MS, RAC Empirical Testing Corp. 719.337.7579
Date Summary was Prepared	20-Jun-2019
Trade or Proprietary Name	MEGAFIX® Pedicle Screw Spinal System
Common or Usual Name	Thoracolumbosacral Pedicle Screw System
Classification	Class II per 21 CFR §888.3070
Product Code	NKB
Classification Panel	Division of Orthopedic Devices

5.1. Description of the Device Subject to Premarket Notification

The MEGAFIX® Pedicle Screw Spinal System is used for posterior, non-cervical pedicle fixation of the lumbar and sacral spine. This system is comprised of monoaxial screws, monoaxial reduction screws, polyaxial screws, polyaxial reduction screws, polyaxial cannulated screws, cannulated reduction screws, straight rods, curved rods, set screws, and transverse link. All components are supplied non-sterile, single use and made from Titanium Alloy (Ti-6A1-4V ELI) that conforms to ASTM F136. Various types and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients. The MEGAFIX® Pedicle Screw Spinal System is delivered non-sterile and sterilization instructions are provided.

The principle of the spinal fixation is based on pedicle screw-rod locking systems, with the rods transversely crosslinked. A combination of pedicle screws and rods creates a solid "brace" that holds spinal segments. Pedicle screws are fixed through the pedicle bone on the posterior spinal column. The pedicle screw is inserted through the pedicle and into the vertebral body, one on each side. The pedicle screws fix to the bone of the vertebral body, giving them a good solid hold on the vertebrae. Once the pedicle screws are implanted, they are attached to rods that connect all the pedicle screws together. When all components are bolted and tightened by set screws, a stiff metal frame that holds vertebrae still is created so that fusion can occur. Bone graft is then placed around the posterior vertebrae at the implant. A transverse link is used to connect two substantially parallel longitudinal rods for improved

stability in the surgical treatment and for increased rotational stiffness for the final construct.

5.2. Indications for Use

The MEGAFIX® Pedicle Screw Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion using autograft or allograft. This system is intended for posterior, non-cervical pedicle fixation of the lumbar and sacral spine for 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 (Grade 1 and 2) of the L5-S1; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

5.3. Technological Characteristics

The MEGAFIX® Pedicle Screw Spinal System is made from Titanium Alloy (Ti-6A1-4V ELI) per ASTM F136. The subject and predicate devices have nearly identical technological characteristics and minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Principle Operation
- Material of manufacture
- Basic design

Table 5-1 Predicate Device

K number	Proprietary Name	Manufacturer	Predicate Type
K131878	Zenius Pedicle Screw System	Medyssey Co., Ltd	Primary
K111362	Rexious Spinal Fixation System	DIOMEDICAL Co., Ltd	Additional
K183080	Mega Plus Spine System	BK MEDITECH Co., Ltd	Additional
K123164	SpineFrontier PedFuse Pedicle Screw System	SpineFrontier, Inc.	Additional
K141282	PSG 5.5mm Cannulated Pedicle Screw System	Pinnacle Spine Group	Additional

5.4. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

5.4.1 Mechanical testing

Mechanical testing was performed on the MEGAFIX® Pedicle Screw Spinal System in accordance with ASTM F1717. The following testing was performed:

- Static Compression Bending
- Static Torsion
- Dynamic Compression Bending

The test results support substantial equivalence of the subject to legally marketed predicate devices.

5.5. Summary of Substantial Equivalence

Based on the comparison, we have demonstrated that the MEGAFIX® Pedicle Screw Spinal System has been shown to be substantially equivalent for the proposed Indications for Use as the legally marketed predicate devices. Therefore, we conclude that the proposed MEGAFIX® Pedicle Screw Spinal System is substantially equivalent to those predicate devices.

5.6. Conclusion

As seen above, the MEGAFIX® Pedicle Screw Spinal System is the same or similar to the predicate devices in terms of intended use, material, principle operation, basic design. The technological differences have been addressed in the 510(k) and performance testing demonstrates substantial equivalence to the identified predicate devices. Therefore, the differences do not raise new questions of safety and effectiveness. The MEGAFIX® Pedicle Screw Spinal System is substantially equivalent to legally marketed predicates.