January 29, 2018

DeGen Medical
% Linda Braddon, Ph.D.
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
Woodstock, Georgia 30188

Re: K173814
Trade/Device Name: DeGen Medical E^3 MIS Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: December 14, 2017
Received: December 15, 2017

Dear Dr. Braddon:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K173814

Device Name
DeGen Medical E3 MIS Pedicle Screw System

Indications for Use *(Describe)*

The DeGen Medical E3 MIS 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; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).When used for posterior noncervical pedicle screw fixation in pediatric patients, the DeGen Medical E3 MIS Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The DeGen Medical E3 MIS Pedicle Screw System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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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510(k) Summary of Safety and Effectiveness

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the DeGen Medical E^3 MIS Pedicle Screw System is provided below.

Date Summary Prepared	January 29, 2018
Submitter	DeGen Medical 1321-C North Cashua Drive Florence, SC 29501 Phone 877-240-7838 Fax 843-407-0545
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 LGB@SecureBME.com
Trade Name	DeGen Medical E^3 MIS Pedicle Screw System
Common Name	Pedicle screw spinal system
Code –Classification	NKB, KWP 21 CFR 888.3070 : Class II
Primary Predicate	K172101 ROMEO 2 Posterior Osteosynthesis System
Additional Predicates	K142531 & K160926 F1 MPS Modular Pedicle Screw System K161363 Alphatec Spine, Inc. Arsenal™ Spinal Fixation System
Device Description	DeGen Medical E^3 MIS Pedicle Screw System composed of cannulated and non-cannulated pedicle screws of various lengths and diameters which are designed to accept a 5.5mm rod in various lengths. The components can be rigidly assembled in a variety of constructs, each corresponding to the needs and anatomy of a specific patient. Additionally, the DeGen Medical E^3 MIS Pedicle Screw System may be used interchangeably with the DeGen Medical F1 MPS system including the CONNECT-L Transverse Connector and JOUST minimally invasive rods. This submission addresses both the the DeGen Medical E^3 MIS Pedicle Screw System and minor design changes for manufacturability of the F1 MPS. The DeGen Medical E^3 MIS Pedicle Screw System is provided non-sterile. The system is constructed from Titanium and Titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and F67 and/or cobalt-chromium-molybdenum per ASTM F1537.

Intended Use	The DeGen Medical E^3 MIS 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; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).When used for posterior noncervical pedicle screw fixation in pediatric patients, the DeGen Medical E^3 MIS Pedicle Screw System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The DeGen Medical E^3 MIS Pedicle Screw System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
Technological Characteristics	As was established in this submission, both additions and minor changes to the F1 MPS are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device, DeGen Medical E^3 MIS Pedicle Screw System, was shown to be substantially equivalent and has the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.
Non-Clinical Performance Testing Conclusion	Non-clinical testing was performed to demonstrate the DeGen Medical E^3 MIS Pedicle Screw System is substantially equivalent to other predicate devices in accordance with "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004. The following tests were performed: • Static and dynamic compression testing per ASTM F1717 • Static torsion testing per ASTM F1717 • Screw pullout strength via ASTM F543 • Static tulip head disassembly via ASTM F1798 • Dynamic flexion-extension testing via ASTM F1798 The results of these studies show the subject DeGen Medical E^3 MIS Pedicle Screw System meets or exceeds the performance of the predicate devices, and the device was therefore found to be substantially equivalent.
Substantial Equivalence Summary (Conclusion)	The subject the DeGen Medical E^3 MIS Pedicle Screw System has been shown to be substantially equivalent to legally marketed predicate devices and can be interchanged with components from the DeGen Medical F1 MPS System and accessories, CONNECT-L Transverse Connector and the JOUST™ minimally invasive rods.