DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 28, 2016

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

Re: K160926
Trade/Device Name: F1 MPS Modular Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, OSH
Dated: April 25, 2016
Received: April 26, 2016

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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: January 31, 2017
See *PRA Statement on last page.*

510(k) Number *(if known)*

K160926

Device Name

F1 MPS Modular Pedicle Screw System

Indications for Use *(Describe)*

The F1 MPS Modular Pedicle Screw System (F1 MPS) is intended for posterior, non-cervical pedicle fixation (T1-S1) 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 thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurological impairment; Severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; Fracture; Dislocation; Spinal stenosis; Scoliosis or kyphotic deformities; Spinal Tumor; Schuermann's disease; Failed previous fusion.

The F1 MPS is intended for posterior, noncervical pedicle fixation (T1-S1) to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.

The F1 MPS is also intended to stabilize the posterior non-cervical fixation in pediatric patients indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The device is intended to be used with autograft and/or allograft.

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)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 F1 MPS Modular Pedicle Screw System with the addition of the Connect-L Transverse Connector and JOUST™ minimally invasive rods line extensions is provided below.

Date Summary Prepared	June 14, 2016
Sponsor	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	F1 MPS Modular Pedicle Screw System
Common Name	Pedicle screw spinal system
Code – Classification	NKB 21 CFR 888.3070 : Class III MNH, MNI, OSH 21 CFR 888.3070 : Class II
Primary Predicate Device	K142531 DeGen Medical F1 MPS Modular Pedicle Screw System
Additional Predicates	K061520, K071860 DePuy Spine Viper Spine System K062196 DePuy Spine SFX Snap-Fit Cross Connector K933881, K953915, K982320, K982511, K982011, K983583, K992168, K011182, K030383 DePuy Moss Miami Spinal System

Device Description	The F1 MPS system is modular 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. This submission addresses the line extension of CONNECT-L Transverse Connector and JOUST minimally invasive rods to the F1 MPS Modular Pedicle Screw System (K142531), and make FDA aware of minor changes to F1 MPS for manufacturability. The CONNECT-L Transverse Connector comes in fixed and variable sizes. The JOUST™ minimally invasive rods are used in a minimally invasive approach. The JOUST™ minimally invasive manual surgical instruments aid in percutaneous approach. Additional 5.5mm rods are added to this system to allow for ease of entry. The F1 MPS 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.
Indications for Use	The F1 MPS Modular Pedicle Screw System (F1 MPS) is intended for posterior, non-cervical pedicle fixation (T1-S1) 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 thoracic, lumbar, and sacral spine: Degenerative spondylolisthesis with objective evidence of neurological impairment; Severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; Fracture; Dislocation; Spinal stenosis; Scoliosis or kyphotic deformities; Spinal Tumor; Schuermann's disease; Failed previous fusion. The F1 MPS is intended for posterior, noncervical pedicle fixation (T1-S1) to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment. The F1 MPS is also intended to stabilize the posterior non-cervical fixation in pediatric patients indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The device is intended to be used with autograft and/or allograft.

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 devices were 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 addition of the subject components to the already cleared DeGen Medical F1 MPS 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 Torsional Gripping Capacity testing per ASTM F1798 The results of these studies show the subject devices 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 DeGen Medical F1 MPS System and components, CONNECT-L Transverse Connector and the JOUST™ minimally invasive rods, have been shown to be substantially equivalent to legally marketed predicate devices.