510(k) SUMMARY

APR 18 2014

Manufacturer:	GS Medical Co., Ltd. 90, Osongsaengmyeong 4-ro Osong-eup Cheongwon-gun Chungcheongbuk-do 363-951 Korea
Date:	April 18, 2014
Submitted by:	GS Medical Co., Ltd
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US Agent Information Official Correspondent	Orgenix LLC Mr. Donald W. Guthner 111 Hill Road Douglassville, PA 19518 +1-646-460-2984 +1-484-363-5879 (FAX) dg@orgenix.com
Classification Name:	Intervertebral Body Fusion Device
Common/Usual Name:	Intervertebral Body Fusion Device, IBF Device
Proprietary Name:	AnyPlus® PEEK ALIF PEEK Lumbar Fusion Cage AnyPlus® PEEK PLIF PEEK Lumbar Fusion Cage AnyPlus® PEEK TLIF PEEK Lumbar Fusion Cage AnyPlus® PEEK TPLIF PEEK Lumbar Fusion Cage
Performance standards:	The GS Medical AnyPlus PEEK Lumbar Cage was non-clinically tested according to the ASTM 2077-03 and ASTM F2267-04 performance standards.
Classification no.:	21 CFR 888.3080 MAX – Intervertebral body fusion device Class II
Substantial Equivalence:	Substantial equivalence for the *GS Medical AnyPlus PEEK Lumbar Cage* is based on its similarities in indications for use, design features, operational principles and material composition when compared to the

predicate devices cleared under the following submissions:

- K111354GS Medical AnyPlus® PEEK Lumbar Cage

Predicate Devices: The subject device is substantially equivalent to similar previously cleared devices.

Device Description: The *GS Medical AnyPlus PEEK Lumbar Cage* device consists of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The implants are made of polyether-ether-ketone (PEEK OPTIMA LT1) (Manufacturer – INVIBIO) body (PEEK conforming to ASTM F2026) with the x-ray markers made of Tantulum (conforming to ASTM F560). This submission includes the addition of sizes to the model PLIF devices, a revision of the shapes of the ALIF, PLIF and TLIF model and the addition of the TPLIF model based on the PLIF design to accommodate surgeons using a Transforaminal Posterior Lateral Interbody Fusion (TPLIF) surgical approach.

Intended Use: The AnyPlus PEEK Lumbar Cage is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The AnyPlus PEEK Lumbar Cage is to be combined with internal supplemental fixation cleared for use in the lumbar spine.

Summary of Technological Characteristics: The GS Medical AnyPlus PEEK Lumbar Cage devices are designed for restoring the height of the intervertebral space after resection of the disc. The AnyPlus PEEK Lumbar Cage devices consist of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The implants are made of polyether-ether-ketone (PEEK) body with the x-ray markers made of Tantulum The intended use, technological characteristics, mode of action and materials of construction are the same as those of the referenced predicate devices

Non-Clinical Testing: The GS Medical AnyPlus PEEK Lumbar Cage devices were tested according to the ASTM 2077, specifically, Static and Dynamic Axial Compression, Static and Dynamic Compression-Shear Testing, Static and Dynamic Torsion Testing Expulsion Testing and Static Subsidence testing under Axial Compression, per ASTM 2267.
All performance test results were equivalent to or higher than a legally marketed predicate device.

Clinical Testing	No clinical testing was performed.
Conclusion	The GS Medical AnyPlus® ALIF PEEK Cage, AnyPlus® PLIF PEEK Cage, AnyPlus® T-PLIF PEEK Cage and AnyPlus® TLIF PEEK Cage have the same intended use and similar indications, principles of operation, and technological characteristics as the GS Medical AnyPlus® ALIF PEEK Cage, AnyPlus® PLIF PEEK Cage and AnyPlus® TLIF PEEK Cage. The minor differences in the designs do not raise any new questions of safety or effectiveness. Performance data demonstrates that the AnyPlus® ALIF PEEK Cage, AnyPlus® PLIF PEEK Cage, AnyPlus® T-PLIF PEEK Cage and AnyPlus® TLIF PEEK Cage are as safe and effective as the AnyPlus® ALIF PEEK Cage, AnyPlus® PLIF PEEK Cage and AnyPlus® TLIF PEEK Cage]. Thus, the AnyPlus® ALIF PEEK Cage, AnyPlus® PLIF PEEK Cage, AnyPlus® T-PLIF PEEK Cage and AnyPlus® TLIF PEEK Cage are substantially equivalent to its predicate devices

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

April 18, 2014

GS Medical Company, Limited
% Orgenix, LLC
Mr. Donald W. Guthner
Regulatory Consultant
111 Hill Road
Douglassville, Pennsylvania 19518

Re: K131612
Trade/Device Name: AnyPlus® ALIF, PLIF, TLIF and TPLIF PEEK Lumbar Fusion Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 19, 2014
Received: March 20, 2014

Dear Mr. Guthner:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131612

Device Name: AnyPlus® ALIF PEEK Cage, AnyPlus® PLIF PEEK Cage, AnyPlus® T-PLIF PEEK Cage and AnyPlus® TLIF PEEK Cage

Indications for Use:

AnyPlus® PEEK Lumbar Fusion Cage device is intended for use with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The AnyPlus PEEK Lumbar Cage is to be combined with internal supplemental fixation cleared for use in the lumbar spine.

Prescription Use _X____ AND/OR Over-The-Counter Use____

(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices