October 8, 2020

PrinterPrezz
℅ Nathan Wright, MS
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K201939
Trade/Device Name: GAIA Lumbar Interbody Fusion Device (LIFD) Family
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 10, 2020
Received: July 13, 2020

Dear Mr. Wright:

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,

Brent Showalter, Ph.D.
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)*
K201939

Device Name
GAIA Lumbar Interbody Fusion Device (LIFD) Family

Indications for Use *(Describe)*

The ASTRAEUS anterior lumbar interbody fusion device is a member of the GAIA family of interbody fusion devices intended for interbody fusion procedures (arthrodesis) in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft.
GAIA devices, including the ASTRAEUS system, are to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.
Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.
Additionally, the ASTRAEUS cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.
The ASTRAEUS ALIF cage is to be implanted via an anterior approach.

The PROMETHEUS Posterior lumbar interbody fusion device is a member of the GAIA family of interbody fusion devices intended for interbody fusion procedures (arthrodesis) in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft.
GAIA devices, including the PROMETHEUS system, are to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.
Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.
Additionally, the PROMETHEUS cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.
The PROMETHEUS PLIF cage is to be implanted via a posterior approach.

The THEMIS Transforaminal posterior lumbar interbody fusion device is a member of the GAIA family of interbody fusion devices intended for interbody fusion procedures (arthrodesis) in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft.
GAIA devices, including the THEMIS system, are to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.
Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.
Additionally, the THEMIS cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.
The THEMIS TPLIF cage is to be implanted via a transforaminal or 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.

5. 510(K) SUMMARY

Submitter's Name:	PrinterPrezz
Submitter's Address:	4110 Clipper Ct. Fremont, CA 94538
Submitter's Telephone:	510-225-8412
Contact Person:	Nathan Wright MS Empirical Consulting 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	10-Jul-2020
Trade or Proprietary Name:	GAIA Lumbar Interbody Fusion Device (LIFD) Family
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The GAIA Lumbar Interbody Fusion Device (LIFD) Family consists of the ASTRAEUS ALIF, the PROMETHEUS PLIF, and the THEMIS TPLIF.

The ASTRAEUS anterior lumbar interbody fusion (ALIF) implants are interbody fusion devices intended for use as an aid in spinal fixation and provide structural stability in skeletally mature patients. The ASTRAEUS ALIF devices are to be implanted via an anterior approach.

The PROMETHEUS posterior lumbar interbody fusion (PLIF) implants are interbody fusion devices intended for use as an aid in spinal fixation and provide structural stability in skeletally mature patients. The PROMETHEUS PLIF devices are to be implanted via a posterior approach.

The THEMIS transforaminal posterior lumbar interbody fusion (TPLIF) implants are interbody fusion devices intended for use an aid in spinal fixation and provided structural stability in skeletally mature patients. THE THEMIS TPLIF devices are to be implanted via a transforaminal or posterior approach.

The GAIA Lumbar Interbody Fusion Device (LIFD) Family implants are manufactured additively from titanium alloy (Ti-6Al-4V) per ASTM F3001 and are offered in a variety of standard sizes (width, length, height, lordotic angle) designed to adapt to many different patient anatomy. Each interbody device has an axial graft window to allow bone grafting material of autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft to be placed inside the interbody. Various interbody window lattices are provided to adapt to various bone graft placement methods. High friction surfaces with protrusions on superior and inferior of the interbody fusion device grip the end plates of adjacent vertebrae to resist

expulsion or other unintended migration of the implant. These implants provide an alternative to autogenous bone graft blocks and assist to reduce complications related to bone graft.

INDICATIONS FOR USE

The ASTRAEUS anterior lumbar interbody fusion device is a member of the GAIA family of interbody fusion devices intended for interbody fusion procedures (arthrodesis) in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

GAIA devices, including the ASTRAEUS system, are to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Additionally, the ASTRAEUS cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The ASTRAEUS ALIF cage is to be implanted via an anterior approach.

The PROMETHEUS Posterior lumbar interbody fusion device is a member of the GAIA family of interbody fusion devices intended for interbody fusion procedures (arthrodesis) in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

GAIA devices, including the PROMETHEUS system, are to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Additionally, the PROMETHEUS cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The PROMETHEUS PLIF cage is to be implanted via a posterior approach.

The THEMIS Transforaminal posterior lumbar interbody fusion device is a member of the GAIA family of interbody fusion devices intended for interbody fusion procedures (arthrodesis) in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

GAIA devices, including the THEMIS system, are to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Additionally, the THEMIS cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The THEMIS TPLIF cage is to be implanted via a transforaminal or posterior approach.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the 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
- Materials of manufacture
- Structural support mechanism
- Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K170676	HD Lumbar Interbody System	HD LifeSciences LLC	Primary
K172816	TiGer Shark™ System	Choice Spine, LP	Additional
K162496	Foundation F3 Interbody	CoreLink, LLC	Additional
K143258	PLIF STS, TLIF STS, and OLIF STS	4WEB, Inc.	Additional
K180556	Foundation 3D Anterior Lumbar System	CoreLink, LLC	Additional
K190483	SPIRA Open Matrix ALIF and LLIF	Camber Spine Technologies	Additional
K111354/K131612	AnyPlus® PEEK Lumbar Fusion Cage	GS Medical Co, Ltd.	Additional

PERFORMANCE DATA

The GAIA Lumbar Interbody Fusion Device (LIFD) Family has been tested in the following test modes:

- Static and dynamic axial compression per ASTM F2077-18
- Static and dynamic compression shear per ASTM F2077-18
- Subsidence per ASTM F2267-04 (2018)

The results of this non-clinical testing show that the strength of the GAIA Lumbar Interbody Fusion Device (LIFD) Family is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the GAIA Lumbar Interbody Fusion Device (LIFD) Family is substantially equivalent to the predicate device.