Astura Medical
Thomas Purcell
Vice President
3186 Lionshead Ave, Suite 100
Carlsbad, California 92010

April 18, 2018

Re: K172947
Trade/Device Name: HALF DOME Posterior Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 21, 2018
Received: March 22, 2018

Dear Mr. Purcell:

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,

Katherine D. Kavlock -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)*

K172947

Device Name

HALF DOME Posterior Lumbar Interbody System

Indications for Use *(Describe)*

The Half Dome Posterior Lumbar Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L1-L2 to L5-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Half Dome implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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: HALF DOME Posterior Lumbar Interbody System

PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) Spacers

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	April 16th, 2018
Submitted By	Astura Medical 3186 Lionshead Ave, Suite 100 Carlsbad, CA 92010 Phone: 760-814-8047
Contact	Thomas Purcell 3186 Lionshead Ave, Suite 100 Carlsbad, CA 92010 Phone: 760-814-8047 Email: thomas@asturamedical.com
Trade Name	HALF DOME Posterior Lumbar Interbody System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral body fusion device – lumbar
Class	II
Product Code	MAX
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	Astura Medical HALF DOME Posterior Lumbar Interbody System (K152512)
Additional Predicate Device(s)	Cutting Edge Spine, LLC EVOS Lumbar Interbody System (K150321)
Device Description	The Half Dome Posterior Lumbar Interbody devices are implants developed for the substitution of the classical autogenous bone graft blocks. The cages assist to avoid complications related to the bone graft donation site (chronic pain, hematoma, infection, bone removal from the donor site making it impossible to remove bone again, quality of the iliac bone, accessing a healthy donor site that may become an unhealthy site, hernias by the incision). They are available in a range of footprints and heights to suit the individual pathology and anatomical conditions of the patient. The implants have a hollow center to allow placement of autogenous bone graft. The superior and inferior surfaces are open to promote contact of the bone graft with the vertebral end plates, allowing bone growth (arthrodesis). The Half Dome cages are designed to be used in conjunction with supplemental spinal fixation instrumentation.
Materials	PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) – MAF 2227 (added material) Tantalum per ASTM F560
Substantial Equivalence Claimed to Predicate	The Half Dome Posterior Lumbar Interbody System PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) Spacers are substantially equivalent to the predicate devices in terms of intended use, design,

Devices	material, and mechanical safety and performances.
Indications for Use	The Half Dome Posterior Lumbar Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L1-L2 to L5-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Half Dome implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic compression per ASTM F2077 • Subsidence per ASTM F2267 The results of these evaluations indicate that the PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) Half Dome implants are equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-Clinical and Clinical	Astura Medical considers the Half Dome Posterior Lumbar Interbody System PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) Spacers to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.