February 27, 2018

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

Re: K173324
Trade/Device Name: ALTA Anterior Cervical Interbody Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 10, 2017
Received: December 15, 2017

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)*
K173324

Device Name
ALTA Anterior Cervical Interbody Spacer

Indications for Use *(Describe)*
The ALTA Anterior Cervical Interbody Spacer is indicated for intervertebral body fusion of the spine in skeletally mature patients. The ALTA Anterior Cervical Interbody Spacer is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

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: ALTA ANTERIOR CERVICAL INTERBODY SPACER

PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced)

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

Date Prepared	January 31st 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	ALTA Anterior Cervical Interbody Spacer
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Body Fusion Device With Bone Graft, Cervical
Class	II
Product Code	ODP
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	Astura Medical ALTA Anterior Cervical Interbody Spacer (K160154)
Additional Predicate Device(s)	SpineFrontier Incorporated, Arena-C HA PEEK Cervical Intervertebral Body Fusion Device (K142026), NuVasive® CoRoent® Small Interbody System (K163491)
Device Description	The ALTA Anterior Cervical Interbody Spacer was developed as implants for the stabilization of the cervical column. The devices have trapezoidal footprints and multiple sizes to accommodate patient anatomy. This device is offered in PEEK OPTIMA LT120HA. The PEEK OPTIMA LT120HA implants have unidirectional teeth on both of their inferior and superior surfaces to prevent migration/expulsion, and graft windows which help facilitate bony integration. X-ray markers are integrated for visualization of the implants during and after surgery. The titanium implants have roughened superior and inferior surfaces to prevent migration of the spacer post implantation.
Materials	PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) – MAF 2227 (added material) Tantalum per ASTM F560
Substantial Equivalence Claimed to Predicate Devices	The PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) ALTA Anterior Cervical Interbody Spacer are substantially equivalent to the predicate devices in terms of intended use, design, material, and mechanical safety and performances.

Indications for Use	The ALTA Anterior Cervical Interbody Spacer is indicated for intervertebral body fusion of the spine in skeletally mature patients. The ALTA Anterior Cervical Interbody Spacer is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic compression per ASTM F2077 • Static and dynamic torsion per ASTM F2077 • Subsidence per ASTM F2267 The results of these evaluations indicate that the PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) ALTA Anterior Cervical Interbody Spacer is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-Clinical and Clinical	Astura Medical considers the PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) ALTA Anterior Cervical Interbody Spacer 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.