October 24, 2019

Astura Medical, LLC
Parker Kelch
Quality Manager
3186 Lionshead Ave, Suite 100
Carlsbad, California 92010

Re: K190426
Trade/Device Name: ALTA Anterior Cervical Corpectomy System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PLR
Dated: October 10, 2019
Received: October 10, 2019

Dear Mr. Kelch:

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,

for Ronald P. Jean, PhD
Director (Acting)
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 below.

510(k) Number *(if known)*

K190426

Device Name

ALTA Anterior Cervical Corpectomy System

Indications for Use *(Describe)*

The ALTA Anterior Cervical Corpectomy Spacer is indicated for vertebral body replacement in the cervical spine (C3-C7) in skeletally mature patients. The Alta Anterior Cervical Corpectomy Spacer is intended to replace a diseased or damaged vertebral body caused by fracture, osteomyelitis, or tumor, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The System is intended to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion. The System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectance is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

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

Date Prepared	October 10, 2019
Submitted By	Astura Medical 3186 Lionshead Ave, Suite 100 Carlsbad, CA 92010 Phone: 760-814-8047
Contact	Parker Kelch Email: quality@asturamedical.com
Trade Name	ALTA Anterior Cervical Corpectomy Spacer
Common Name	vertebral body replacement device
Classification Name	vertebral body replacement device – cervical
Class	II
Product Code	PLR
CFR Section	21 CFR section 888.3060
Device Panel	Orthopedic
Primary Predicate Device	NuVasive Monolith Cervical Corpectomy System (K180550)
Secondary Predicate Device	ALTA Anterior Cervical Interbody Spacer (K160154, K173324)
Device Description	The ALTA Anterior Cervical Corpectomy Spacer is a vertebral body replacement system manufactured from PEEK-OPTIMA LT120HA (HA PEEK) or titanium alloy (Ti6Al4VELI). The devices have trapezoidal footprints and multiple sizes to accommodate patient anatomy and graft windows to help facilitate bony integration. The HA PEEK spacers have unidirectional teeth on both of their inferior and superior surfaces to prevent migration/expulsion and X-ray markers in the form of tantalum pins. The titanium alloy spacers have roughened superior and inferior surfaces to prevent migration/expulsion.
Materials	PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) – MAF 2227 (added Material) Tantalum per ASTM F560 Titanium alloy (Ti-6Al-4V ELI) per ASTM F136
Substantial Equivalence Claimed to Predicate Devices	The ALTA Anterior Cervical Corpectomy System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The ALTA Anterior Cervical Corpectomy Spacer is indicated for vertebral body replacement in the cervical spine (C3-C7) in skeletally mature patients. The Alta Anterior Cervical Corpectomy Spacer is intended to replace a diseased or damaged vertebral body caused by fracture, osteomyelitis, or tumor, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The System is intended to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or

	corticocancellous bone graft as an adjunct to fusion. The System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectance is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.
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 Alta Corpectomy implants are equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-Clinical and Clinical	Astura Medical considers the ALTA Anterior Cervical Corpectomy 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.