October 26, 2020

Astura Medical, LLC
Mr. Parker Kelch
Quality Manager
4949 W Royal Ln.
Irving, Texas 75063

Re: K202065
Trade/Device Name: DOLOMITE Anterior Cervical Stabilization System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: July 23, 2020
Received: July 27, 2020

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,

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 below.

510(k) Number *(if known)*

K202065

Device Name
DOLOMITE Anterior Cervical Stabilization System

Indications for Use *(Describe)*

The DOLOMITE Stand-Alone Cervical Interbody Spacer is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at disc levels (C2-T1). Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should have at least six weeks of nonoperative treatment prior to treatment with intervertebral cages. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

The Dolomite Spacer is an interbody fusion device intended to be used with supplemental fixation for one or two levels of the cervical spine.

The DOLOMITE Spacer and Plate assembly are an integrated interbody fusion device intended for stand-alone use at one or two levels of the cervical spine (C2-T1) and used with titanium alloy screws. Multiple full plate assembly configurations can't be used in conjunction for two contiguous levels of the cervical spine. When used with anchors, the assembly is intended for use at one level of the cervical spine with additional supplemental fixation that has been cleared by the FDA for use in the cervical spine.

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	June 26, 2020
Submitted By	Astura Medical 4949 W Royal Ln Irving, TX 75063 Phone: 469-501-5530
Contact	Parker Kelch Email: quality@asturamedical.com
Trade Name	DOLOMITE Anterior Cervical Stabilization System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral body fusion device – cervical
Class	II
Product Code	OVE, ODP
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	Astura Medical ALTA Anterior Cervical Interbody Spacer (K160154)
Secondary Predicate Device	Globus COALITION Spacer (K173115); Globus HEDRON Cervical Spacer (K191243); LDR Spine Cervical Interbody Fusion System (K091088)
Device Description	The DOLOMITE Anterior Cervical Stabilization System are implants developed for the stabilization of the cervical column. The spacers are a 2-piece modular design which allows for interchangeable plate and spacer components. The plate and spacer components contain interlocking features in addition to a locking mechanism which allows for intraoperative assembly prior to implantation. The spacer components are available in a range of footprints and heights in PEEK OPTIMA LT120HA or machined Titanium alloy. The plates are offered in multiple fixation types and sizes to suit the individual pathology and anatomical conditions of the patient in machined Titanium alloy. 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 to allow bone growth.
Materials	PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) Tantalum per ASTM F560 Titanium alloy (Ti-6Al-4V ELI) per ASTM F136 Nitinol #1 (ASTM F2063)
Substantial Equivalence Claimed to Predicate Devices	The DOLOMITE Stand-Alone Cervical System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performance.
Indications for Use	The DOLOMITE Stand-Alone Cervical Interbody Spacer is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at disc levels (C2-T1). Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should have at least six weeks of nonoperative treatment prior to treatment with intervertebral cages. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

	The Dolomite Spacer is an interbody fusion device intended to be used with supplemental fixation for one or two levels of the cervical spine. The DOLOMITE Spacer and Plate assembly are an integrated interbody fusion device intended for stand-alone use at one or two levels of the cervical spine (C2-T1) and used with titanium alloy screws. Multiple full plate assembly configurations can't be used in conjunction for two contiguous levels of the cervical spine. When used with anchors, the assembly is intended for use at one level of the cervical spine with additional supplemental fixation that has been cleared by the FDA for use in the cervical spine.
Non-clinical Test Summary	The following analyses were conducted: • Dynamic Compression • Static Compression • Dynamic Torsion • Static Torsion The results of these evaluations indicate that the Dolomite implants are equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-Clinical and Clinical	Astura Medical considers DOLOMITE Anterior Cervical Stabilization System 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.