March 30, 2022

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

Re: K214047
Trade/Device Name: EL CAPITAN Anterior Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 17, 2022
Received: March 17, 2022

Dear Parker 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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214047

Device Name
EL CAPITAN ANTERIOR LUMBAR INTERBODY SYSTEM

Indications for Use *(Describe)*
The El Capitan Anterior 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). El Capitan System 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.

The EL CAPITAN Spacer and Plate assembly are an integrated interbody fusion device intended for stand-alone use when used with all titanium alloy screws. When used with anchors only the zero plate may be used and the assembly is intended for use with additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine.

Hyperlordotic interbody devices (>20° lordosis) and the Oblique interbody devices must be used with supplemental fixation (e.g. posterior fixation) that has been cleared by the FDA for use in the lumbar 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.

510(k) Summary: EL CAPITAN Anterior Lumbar Interbody Fusion

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

Date Prepared	March 16, 2022
Submitted By	Astura Medical 4949 W Royal Ln Irving, TX 75063
Contact	Parker Kelch 4949 W Royal Ln Irving, TX 75063 Phone: 469-501-5530 x503 Email: quality@asturamedical.com
Trade Name	EL CAPITAN Anterior Lumbar Interbody Fusion System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral body fusion device – lumbar
Class	II
Product Code	OVD
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	EL CAPITAN Anterior Lumbar Interbody Fusion (K192492)
Additional Predicate Device(s)	Half Dome (K152512, K182877) Spinal Elements Lucent Magnum (K083475)
Device Description	The El Capitan Anterior 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). 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 spring-loaded latch mechanism which allows for intraoperative assembly prior to implantation. The spacer components are available in a range of footprints and heights, and the plates are offered in multiple fixation types and sizes 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).
Materials	PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced) – MAF 2227 Tantalum per ASTM F560 Titanium Alloy (Ti6-AL4-V ELI) per ASTM F136 Nitinol #1 (ASTM F2063)

Substantial Equivalence Claimed to Predicate Devices	The El Capitan Anterior Lumbar Interbody System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The El Capitan Anterior 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). El Capitan System 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. The EL CAPITAN Spacer and Plate assembly are an integrated interbody fusion device intended for stand-alone use when used with all titanium alloy screws. When used with anchors only the zero plate may be used and the assembly is intended for use with additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine. Hyperlordotic interbody devices (>20° lordosis) and the Oblique interbody devices must be used with supplemental fixation (e.g. posterior fixation) that has been cleared by the FDA for use in the lumbar spine.
Non-clinical Test Summary	The following analyses were conducted: • Static Compression ASTM F2077 • Dynamic Compression ASTM F1717 • Static Compression Shear ASTM F2077 • Dynamic Compression Shear ASTM F1717 • Subsidence ASTM F2267 • Expulsion The results of these evaluations indicate that the El Capitan implants are equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-Clinical and Clinical	Astura Medical considers the El Capitan Anterior Lumbar Interbody 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.