DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2016

Astura Medical
% Mr. J.D. Webb
President
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K160154
Trade/Device Name: ALTA Cervical Interbody Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: March 25, 2016
Received: March 29, 2016

Dear Mr. Webb:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K160154

Device Name

ALTA Cervical Interbody Spacer

Indications for Use *(Describe)*

The ALTA 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. This device is intended for use with supplemental internal fixation systems and autogenous bone graft implanted via an open, anterior approach. Patients should have at least six weeks of non-operative treatment prior to treatment with intervertebral cages.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

*5*10(k) Summary: ALTA Cervical Interbody Spacer

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

Date Prepared	March 25, 2016
Submitted By	Astura Medical, LLC 5670 El Camino Real, Suite B Carlsbad, CA 92008 760-814-8047 Tele
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele 512-692-3699 Fax e-mail: jdwebb@orthomedix.net
Trade Name	ALTA Cervical Interbody Spacer
Common Name	intervertebral body fusion device
Classification Name	Intervertebral body fusion device – cervical
Class	II
Product Code	ODP
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	Spinal Elements, Crystal Cervical Cage (K073351)
Additional Predicate Devices	Titan, Endoskeleton® TC (K100889) Zimmer, BAK/C Vista Interbody Fusion (P980048 S3) LDR Spine Cervical Interbody Fusion System (K091088) Titan Spine Endoskeleton TC (K100889)
Device Description	The ALTA 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 two material choices: PEEK and titanium. The PEEK 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	Vestakeep® i4R PEEK conforming to ASTM F2026 Unalloyed tantalum conforming to ASTM F560 Titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136
Substantial Equivalence Claimed to Predicate Devices	The ALTA Cervical Interbody Spacer is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The ALTA 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. This device is intended for use with supplemental internal fixation systems and autogenous bone graft implanted via an open, anterior approach. Patients should have at least six weeks of non-operative treatment prior to treatment with intervertebral cages.
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 • Expulsion testing per ASTM F04.25.02.02 The results of these evaluations indicate that the ALTA Cervical Interbody Spacer is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Astura Medical, LLC considers the ALTA 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.