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

October 2, 2017

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

Re: K171250
Trade/Device Name: BRIDALVEIL Occipital Cervical Thoracic System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: September 1, 2017
Received: September 6, 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.

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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

Ronald P. Jean -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171250

Device Name
BRIDALVEIL Occipital Cervical Thoracic System

Indications for Use *(Describe)*
The BRIDALVEIL Occipital Cervical Thoracic System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (Cl to C7) and the thoracic spine from Tl-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The BRIDALVEIL Occipital Cervical Thoracic 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 expectancy is of insufficient duration to permit achievement of fusion.
In order to achieve additional levels of fixation, the BRIDALVEIL Occipital Cervical Thoracic System may be connected to the OLYMPIC Posterior Spinal Fixation System rods and connectors. Transition rods with differing diameters may also be used to connect the BRIDALVEIL Occipital Cervical Thoracic System to the OLYMPIC Posterior Spinal Fixation System. Refer to the OLYMPIC Posterior Spinal Fixation System package insert for instructions for use and indications for use.

Type of Use *(Select one or both, as applicable)*

[X] 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: BRIDALVEIL Occipital Cervical Thoracic System

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

Date Prepared	September 1, 2017
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	BRIDALVEIL Occipital Cervical Thoracic System
Common Name	Occipital Cervical Thoracic System
Classification Name	Othosis, Cervical Pedicle Screw Spinal Fixation Spinal interlaminal fixation orthosis
Class	Unclassified
Product Code	NKG KWP
CFR Section	N/A
Device Panel	Orthopedic
Primary Predicate Device	Medtronic VERTEX® Reconstruction System - K143471, K152338
Secondary Predicate Devices	NuVasive® VuePoint® OCT System - K150474, K153336 Zimmer Spine Virage® OCT Spinal Fixation System - K153631 Ulrich GmbH neon^{3}™ universal OCT spinal stabilization - K150650 Blackstone Ascent POCT System – K073654
Reference Devices	Alphatec Spine Solanas™ Posterior Stabilization System - (K052201) Alphatec Spine Solanas Avalon Posterior Fixation System (K111076) Medtronic VERTEX® Reconstruction System - K123906 NuVasive® VuePoint® OCT System - K093319 Synthes Spine Synapse System - K070573, K091689, K141897 DePuy Spine MOUNTAINEER® OCT Spinal System - K110353, K132332 Stryker Spine OASYS® System - K142741, K111719, K032394 Orthofix Inc. Centerion POCT System - K131833 LnK Cervical Screw System - K143278
Device Description	The BRIDALVEIL Occipital Cervical Thoracic System is a spinal fixation system intended to stabilize the uppermost portion of the spine during the fusion process. The system contains a wide variety of implants and instruments which allows for the transition across multiple spinal segments: Occipital Plate with Screws, Cervical Polyaxial Screws, Laminar Hooks, Cross Connectors, Rod Connectors, and Rods manufactured from Ti6Al4V ELI (ASTM F136) and cobalt chrome alloy (ASTM F1537).
Materials	Ti-6Al-4V ELI (ASTM F136) CoCrMo alloy (ASTM F1537) Elgiloy CoCrNi alloy (ASTM F1058) Nitinol #1 (ASTM F2063)

Substantial Equivalence Claimed to Predicate Devices	The BRIDALVEIL Occipital Cervical Thoracic System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The BRIDALVEIL Occipital Cervical Thoracic System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The BRIDALVEIL Occipital Cervical Thoracic 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 expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the BRIDALVEIL Occipital Cervical Thoracic System may be connected to the OLYMPIC Posterior Spinal Fixation System rods and connectors. Transition rods with differing diameters may also be used to connect the BRIDALVEIL Occipital Cervical Thoracic System to the OLYMPIC Posterior Spinal Fixation System. Refer to the OLYMPIC Posterior Spinal Fixation System package insert for instructions for use and indications for use.
Non-clinical Test Summary	The following analyses were conducted: • Static Compression Bending – ASTM F1717 • Dynamic Compression Bending – ASTM F1717 • Static Torsion – ASTM F1717 • Static Compression Bending – ASTM F2706 • Dynamic Compression Bending – ASTM F2706 • Static Torsion – ASTM F2706 • Dynamic Torsion – ASTM F2706 • Static Axial Grip – ASTM F1798 • Static Torsional Grip – ASTM F1798 • Static Transverse Moment – ASTM F1798 The results of these evaluations indicate that the BRIDALVEIL Occipital Cervical Thoracic System is equivalent to the predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-Clinical and Clinical	Astura Medical considers the BRIDALVEIL Occipital Cervical Thoracic 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.