January 4, 2019

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

Re: K182982
Trade/Device Name: BridalVeil Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 6, 2018
Received: December 7, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182982

Device Name
BRIDALVEIL NAVIGATED INSTRUMENTS

Indications for Use *(Describe)*

The BRIDALVEIL NAVIGATED INSTRUMENTS are intended to be used in the preparation and placement of BRIDALVEIL screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: BRIDALVEIL NAVIGATED INSTRUMENTS

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

Date Prepared	October 26, 2018
Submitted By	Astura Medical 3186 Lionshead Ave, Suite 100 Carlsbad, Ca 92010 Phone: 760-814-8047
Contact	Parker Kelch 3186 Lionshead Ave, Suite 100 Carlsbad, Ca 92010 Phone: 760-814-8047 Email: quality@asturamedical.Com
Trade Name	BRIDALVEIL Navigated Instruments
Common Name	Navigated instruments
Classification Name	Stereotaxic instrument
Class	Class II
Product Code	OLO
Cfr Section	21 CFR Section 882.4560
Device Panel	Orthopedic
Primary Predicate Device	Medtronic Instruments (K143628, K143375, K140454)
Reference Device(s)	BRIDALVEIL Occipital Cervical Thoracic System, (Screws) (K171250) OLYMPIC Navigated Instruments (K172166)
Device Description	The BRIDALVEIL Navigated Instruments are comprised of nonsterile, reusable instruments including taps and drivers that can be operated manually. These instruments are intended to be used with the Medtronic StealthStation® System (v 2.1.0) and are manufactured from stainless steel, as specified in ASTM F899.
Materials	Stainless Steel per ASTM F899
Substantial Equivalence Claimed to Predicate Devices	The BRIDALVEIL Navigated Instruments are substantially equivalent to the predicate BRIDALVEIL devices in terms of intended use, materials used, mechanical safety and performances. The changes in design on the instruments are the addition of a Navlock feature, this is equivalent to the Navlock found on Medtronic Navigated instruments and intended for use with the Medtronic StealthStation® System.
Indications for Use	The BRIDALVEIL NAVIGATED INSTRUMENTS are intended to be used in the preparation and placement of BRIDALVEIL screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
NON-CLINICAL TEST SUMMARY	The following analyses were conducted: • Dimensional analysis compared to predicate

	• Anatomical simulated use and navigation accuracy The results of these evaluations indicate that the BRIDALVEIL NAVIGATED INSTRUMENTS are equivalent to the predicate devices.
CLINICAL TEST SUMMARY	No clinical studies were performed
CONCLUSIONS: NON-CLINICAL AND CLINICAL	Astura medical considers the BRIDALVEIL NAVIGATED INSTRUMENTS 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.