April 27, 2018

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

Re: K172166
Trade/Device Name: OLYMPIC Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 29, 2018
Received: March 30, 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. 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.

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172166

Device Name
OLYMPIC NAVIGATED INSTRUMENTS

Indications for Use *(Describe)*
The OLYMPIC NAVIGATED INSTRUMENTS are intended to be used in the preparation and placement of OLYMPIC PSFS 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.

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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: OLYMPIC NAVIGATED INSTRUMENTS

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

Date Prepared	July 17, 2017
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 x413 Email: quality@asturamedical.com
Trade Name	Olympic 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)	OLYMPIC Posterior Spinal Fixation System (Screws), K143446
Device Description	The OLYMPIC 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 OLYMPIC NAVIGATED INSTRUMENTS are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The OLYMPIC NAVIGATED INSTRUMENTS are intended to be used in the preparation and placement of OLYMPIC PSFS 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 OLYMPIC 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 OLYMPIC 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.