January 4th, 2021

ChoiceSpine, LLC
Kim Finch
Director of Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37919

Re: K203561
Trade/Device Name: ChoiceSpine Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 2, 2020
Received: December 7, 2020

Dear Kim Finch:

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: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K203561

Device Name
ChoiceSpine Navigation System

Indications for Use *(Describe)*
The ChoiceSpine Navigation reusable instruments are intended to be used during preparation and placement of ChoiceSpine Lancer™, Thunderbolt™, and Blackbird™ system during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The ChoiceSpine Navigation reusable instruments are specifically designed for use with the Medtronic Stealth Station System (V2.1.0), 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, along bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

☒ 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."

7. 510(k) Summary

Date:	December 2, 2020
Sponsor:	ChoiceSpine, LLC 400 Erin Drive Knoxville, TN 37919
Phone:	865-243-3969
Fax:	865-246-3334
Contact Person:	Kim Finch, Director of Regulatory Affairs
Proposed Proprietary Trade Name:	ChoiceSpine Navigation System
Product Class:	Class II
Classification Name:	ChoiceSpine Navigation System • 882.4560 Neurological Stereotaxic Instrument
Device Product Code:	ChoiceSpine Navigation System • OLO

Purpose of Submission: The purpose of this submission is to add Blackbird instruments to the ChoiceSpine Navigation system.

Device Description: The ChoiceSpine Navigation instruments are non-sterile, reusable instruments designed to function with the Medtronic® StealthStation® System and SureTrak® II System. Refer to the appropriate navigation system Instructions for Use and/or Surgical Technique Guide for details regarding navigation system use. The ChoiceSpine Navigation instruments are for use with ChoiceSpine screw systems, specifically, Lancer™, Thunderbolt™, and Blackbird™ Spinal Systems.

Indications for Use: The ChoiceSpine Navigation reusable instruments are intended to be used during preparation and placement of ChoiceSpine Lancer™, Thunderbolt™, and Blackbird™ system during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The ChoiceSpine Navigation reusable instruments are specifically designed for use with the Medtronic Stealth Station System (V2.1.0), 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, along bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

Materials: The instruments are manufactured from medical grade titanium and stainless steel.

Non-clinical Testing: Addition of Blackbird to Choicespine Navigation does not require testing. The subject and predicate devices have nearly identical technological characteristics the minor difference does not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and

predicate; Principle of operation and technical characteristics such as design, sterility, and interfacing. The only difference between the subject and predicate device is anatomical location of surgical use. The predicate submission names system used in the thoracic lumbar region of the spine (Lancer™/Thunderbolt™) whereas this subject submission will add usage in the cervical region (Blackbird™) as well as the thoracic lumbar region of the spine (Lancer™/Thunderbolt™). The Choice Spine Navigation instruments are specifically 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. Thus the Medtronic® StealthStation® System inherently has the ability for stereotactic surgery of the cervical spine, such as the proposed usage of the ChoiceSpine Blackbird™ system in an identical or similar registration, calibration and application to that of the existing ChoiceSpine Navigation system. Testing is not required since the subject device has identical and unchanged technological characteristics and function as the predicate which was tested per ASTM F2554-10, "Standard Practice for Measurement of Positional Accuracy of Computer assisted Surgical Systems" as part of the original submission.

Predicate Devices:

Primary Predicate:
Navigation System (K182721)
Additional Predicates:
Blackbird™ Spinal System (K133214)
Medtronic Navigated Disc Prep Instruments and CAPSTONE Trials (K150231)

Substantial Equivalence Conclusion:

The addition of Blackbird to Navigation is within scope of the primary and secondary predicates. The Primary predicate submission names system used in the thoracic lumbar region of the spine (Lancer™/Thunderbolt™) whereas this subject submission will add usage in the cervical region (Blackbird™) as well as the thoracic lumbar region of the spine (Lancer™/Thunderbolt™). The secondary predicate (K150231) includes usage in both the Cervical and thoracic lumbar region. So, subject submission is within scope of both the primary and secondary predicates. This subject submission has identical and unchanged technological characteristics and function as the primary predicate.

PERFORMANCE DATA:

The Navigation System has been tested per ASTM F2554-10, "Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems". The results of this non-clinical testing show that performance of the Navigation System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION:

The overall technology characteristics and performance data lead to the conclusion that the Navigation System is substantially equivalent to the predicate device.