January 8, 2019

Choice Spine, LP.
℅ Meredith May
Regulatory and Quality Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K182721
Trade/Device Name: Choice Spine Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 19, 2018
Received: December 20, 2018

Dear Meredith May:

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K182721

Device Name
Choice Spine Navigation System

Indications for Use *(Describe)*

The Choice Spine Navigation reusable instruments are intended to be used during preparation and placement of Choice Spine Lancer™ and Thunderbolt™ system screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Choice Spine Navigation reusable 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, 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)

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)*

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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510(K) SUMMARY

Submitter's Name	Choice Spine, LP.
Submitter's Address	400 Erin Dr. Knoxville, TN 37919
Submitter's Phone	865.246.3333
Contact Person	Meredith Lee May Empirical Consulting 719.337.7579 mmay@empiricalconsulting.com
Date Summary was Prepared	03 January 2019
Trade or Proprietary Name	Choice Spine Navigation System
Common or Usual Name	Orthopedic Stereotaxic Instrument
Classification	Class II per 21 CFR §882.4560
Product Code	OLO
Classification Panel	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Choice Spine Navigation instruments are non-sterile, reusable instruments designed to function with the Medtronic® StealthStation® System and SureTrak® II System. The Choice Spine Navigation instruments are for use with Choice Spine pedicle screw systems, specifically, the Lancer™ and Thunderbolt™ Pedicle Screw Systems. The instruments are manufactured from medical grade titanium and stainless steel.

INDICATIONS FOR USE

The Choice Spine Navigation reusable instruments are intended to be used during preparation and placement of Choice Spine Lancer™ and Thunderbolt™ system screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Choice Spine Navigation reusable 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, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The indications for use for the Choice Spine Navigation is similar to that of the predicate devices noted in Table 5-1: Predicate Devices.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Principle of Operation
- Technical Characteristics
    - Sterility
    - Interfacing
    - Sizes

The only difference between the subject and predicate device is the subject device utilizes different materials than the predicate device, which manufactured only from stainless steels. In addition to stainless steel, the subject device has Radel, Ketaspire KT-820 CF30, Ti-6Al-4V per ASTM F136 and PTFE.

Table 5-1: Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K150231	Navigated Disc Prep Instruments	Medtronic	Primary
K132049	Thunderbolt and Lancer Pedicle Screw System	Choice Spine, LP	Additional
K124004	Navigated CD HORIZON® SOLERATM Screwdrivers, CD HORIZONO SOLERATM Taps, CD HORIZON® SOLERATM Iliac Taps and CD HORIZONO LEGACYTM Taps	Medtronic Navigation, Inc	Reference

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.