September 27, 2019

Precision Spine
℅ Ms. Meredith May
Partnership Manager
Empirical Consulting LLC
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K181606
Trade/Device Name: Precision Spine Navigation Instrumentation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 4, 2019
Received: September 5, 2019

Dear Ms. 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/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,

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

# 4. INDICATIONS FOR USE STATEMENT

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>Food and Drug Administration<br>**Indications for Use** | Form Approved: OMB No. 0910-0120<br>Expiration Date: 06/30/2020<br>*See PRA Statement on last page.* |
|---|---|

510(k) Number *(if known)*
K181606

Device Name
Precision Spine Navigation Instrumentation

Indications for Use *(Describe)*

Precision Spine Navigation Instrumentation are intended to be used during the preparation and placement of Precision Spine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Precision Spine Navigation Instrumentation are specifically designed for use with the Medtronic Stealth Station 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 for 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.**

# 5. 510(K) SUMMARY

| | |
|---|---|
| Submitter's Name: | Precision Spine |
| Submitter's Address: | 2050 Executive Drive<br>Pearl, MS 39208 |
| Submitter's Telephone: | 973-455-7150 |
| Contact Person: | Meredith L May RAC<br>Empirical Consulting LLC<br>719-337-7579 |
| Date Summary was Prepared: | 12 Jun 18 |
| Trade or Proprietary Name: | Precision Spine Navigation Instrumentation |
| Common or Usual Name: | Orthopedic Stereotaxic Instrument |
| Classification: | Class II per 21 CFR §882.4560 |
| Product Code: | OLO |
| Classification Panel: | Orthopedics |

## DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

Precision Spine Navigated Instruments are non-sterile, reusable instruments that can be operated manually. These instruments are intended to be used with the Medtronic StealthStation® System to aid in implantation of associated Precision Spine screw implants. The instruments are manufactured from stainless steel per ASTM F899.

## INDICATIONS FOR USE

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## TECHNOLOGICAL CHARACTERISTICS

Precision Spine Navigated Instruments are non-sterile, reusable instruments that can be operated manually. These instruments are intended to be used with the Medtronic StealthStation® System to aid in implantation of associated Precision Spine screw implants. The instruments are manufactured from stainless steel per ASTM F899.

Precision Spine Navigation Instrumentation is made from material that conforms to ASTM. 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
- Materials of manufacture
- Structural support mechanism

Table 5-1 Predicate Devices

| 510k Number | Trade or Proprietary or Model Name | Manufacturer | Predicate Type |
|---|---|---|---|
| K153603 | Alphatec Spine Navigation Instruments | Alphatec Spine, Inc. | Primary |
| K140454 | Navigated CD HORIZON® SOLERA® Screwdrivers and Taps | Medtronic Sofamor Danek, USA Inc. | Additional |
| K121172 | Reform Pedicle Screw System | Spinal USA | Reference |
| K173130 | Reform® Midline Cortical Screw System | Precision Spine | Reference |

## PERFORMANCE DATA

The following testing was performed:

- Accuracy and Precision Testing of Navigation System per ASTM F2554-10 *Standard Practice for Measurement of Positional Accuracy of computer Assisted Surgical Systems*
- Mating Interface Assessments
- CMM Inspection
- Instrument Verification
- Simulated Use

The accuracy and precision testing of the position and orientation of the Precision Spine Navigation Instrumentation when used with Medtronic's O-Arm, StealthStation, and NavLock Spinal Instruments systems was performed, per ASTM F2554-10, *Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical System*s

## CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Precision Spine Navigation Instrumentation is substantially equivalent to the predicate device.