July 14, 2022

Precision Spine, Inc.
% Nathan Wright
Engineer and Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K220862
Trade/Device Name: E-GPS Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 15, 2022
Received: June 16, 2022

Dear Nathan Wright:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220862

Device Name
E-GPS Navigated Instruments

Indications for Use *(Describe)*

The E-GPS Navigated Instruments are indicated for use 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. The E-GPS Navigated Instruments are reusable and are specifically designed for use with the Globus Medical Excelsius GPS® Robotic Navigation Platform which is intended for use as an aid for precisely locating anatomical structures and for the special positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. Use of the E-GPS Navigated Instrument System is limited to use only with the Reform® Spinal Fixation System (Reform® Ti, Reform® Ti Modular, Reform® Ti CT Modular MIS, Reform® Modular, and Reform® MC).

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

K220862 - 510(K) SUMMARY

Submitter's Name:	Precision Spine, Inc.
Submitter's Address:	2050 Executive Drive Pearl, Mississippi 39208
Submitter's Telephone:	1-601-420-4244
Contact Person:	Nathan Wright MS Empirical Testing Corp. 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	March 22, 2022
Trade or Proprietary Name:	E-GPS Navigated Instruments
Common or Usual Name:	Orthopedic Stereotaxic Instruments
Classification:	Class II per 21 CFR §882.4560
Product Code:	OLO
Classification Panel:	Orthopedic – Stereotaxic, Trauma and Restorative Devices (DHT6C)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

Precision Spine E-GPS Navigated Instruments are non-sterile, reusable instruments including taps and drivers that can be operated manually. These instruments are intended to be used with the Globus Medical Excelsius GPS® Robotic Navigation Platform 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

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

- Device design and dimensions
- Indications for use
- Materials of manufacture
- Principles of operation

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K171651	EXCELSIUS GPS™	Globus Medical Inc.	OLO	Primary
K200303	Reform Pedicle Screw System	Precision Spine	NKB, KWP	Additional
K173130	Reform® Midline Cortical Screw System	Precision Spine, Inc.	NKB	Additional

PERFORMANCE DATA

The E-GPS Navigated Instruments have been evaluated through an engineering analysis and geometric comparison to predicate devices to establish the safety and efficacy for accuracy performance.

The results of this engineering analysis show that the subject is substantially equivalent to the cleared predicate.

CONCLUSION

The overall technology characteristics and engineering analysis lead to the conclusion that the E-GPS Navigated Instruments are substantially equivalent to the predicate device.