February 24, 2021

Practical Navigation, LLC
% Roger White
President
Phiama, Inc
236 McKinley Park Lane
Louisville, Colorado 80027

Re: K202184
Trade/Device Name: Practical Navigation Surgical Guidance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 22, 2021
Received: January 25, 2021

Dear Roger White:

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, MPH
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)*
K202184

Device Name

Practical Navigation Surgical Guidance System

Indications for Use *(Describe)*

The Practical Navigation Surgical Guidance System is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool holder or Guide Tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on an O-arm scan. The Practical Navigation Surgical Guidance System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (L1-S1).

The system is designed for lumbar pedicle screw placement with the patient in the prone position and is compatible with the Integrity LineSider Pedicle Spinal System.

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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510(k) Summary
Practical Navigation Surgical Guidance System

1. Submitter Information

Submitter: Practical Navigation, LLC
Address: 720 E. Wiggins Street
Superior, CO 80027
Telephone: (303) 517-0506
Telefax: N/A

Contact: Roger N. White
rwhite@phiama.com
(303) 550-2451

Date Prepared: February 24, 2021

2. Device Information

Trade Name: Practical Navigation Surgical Guidance System
Common Name: Stereotaxic Instrument
Classification: Class II per 21 CFR 882.4560
Classification Name: Stereotaxic Instrument
Product Code: OLO

3. Purpose of Submission

The purpose of this submission is to gain clearance for a new Image Guided System, the Practical Navigation Surgical Guidance System.

4. Predicate Device Information

The Practical Navigation Surgical Guidance System described in this submission is substantially equivalent to the following predicate:

Predicate Device	**Manufacturer**	**510(k) No.**
Excelsius GPS	Globus Medical, Inc.	K171651

The following device is referenced in this submission:

Reference Device	**Manufacturer**	**510(k) No.**
LineSider™ Spinal System	Integrity Implants, Inc.	K203367

5. Device Description

The Practical Navigation Surgical Guidance System (PNSGS) is an image guided system primarily comprised of a computer workstation, software, a trajectory system, including a targeting platform, a Camera, and various image guided instruments intended for assisting the surgeon in placing screws in the pedicles of the lumbar spine. The PNSGS system allows for registration of the patient's anatomy to O-arm images. Once the patient anatomy is registered, a surgical plan can be created and optically-tracked surgical instruments can be used to follow the surgical plan. The system is used in the following manner:

1. The patient is placed in the appropriate position on the OR table.
2. The compact tracking Camera is rigidly affixed to the OR table using a multi-functional mechanical support arm in the appropriate position to track the surgical site.
3. The Camera is also affixed to a pin placed in the patient's iliac to provide a fixed location relative to the patient's spinal anatomy.
4. The Targeting Platform is affixed to the OR Table using a multi-functional mechanical support arm, ensuring that the Targeting Platform has sufficient range of motion to be placed over the surgical site.
5. The Registration Array is affixed to planned surgical site.
6. The appropriate area of spine is scanned with an O-arm.
7. The scans are transferred to the PNSGS workstation, which reconstructs the images and uses the registration array image to register the patient's spine relative to the Camera location.
8. The registration is confirmed by placing an image guided instrument with a Tracking Array at various points in the surgical field.
9. The surgical paths are planned on the workstation.
10. The Targeting Platform is gross-positioned manually close to the first surgical plan location.
11. The Targeting Platform is activated to set the fine location and the trajectory based on the surgical plan.
12. Instruments with tracking arrays are used through the tool guide of the Targeting Platform to prepare the pedicle and place a pedicle screw.

6. Indications for Use

The Practical Navigation Surgical Guidance System is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool holder or Guide Tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on an O-arm scan. The Practical Navigation Surgical Guidance System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (L1-S1).

The system is designed for lumbar pedicle screw placement with the patient in the prone position and is compatible with the Integrity LineSider Pedicle Spinal System.

7. Comparison of Technological Characteristics

The substantial equivalence of the Practical Navigation Surgical Guidance System to the predicate devices is shown by the similarity in intended use, indications for use, mechanism of action, mode of operation, and performance. The table below provides a comparison of technological characteristics and principles of operation of the PNSGS and the predicate system:

Feature	Practical Navigation Surgical Guidance System (Subject Device)	Globus Medical, Inc. Excelsius GPS (K171651)
Indications for Use:	The Practical Navigation Surgical Guidance System is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool holder or Guide Tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on an O-arm scan. The Practical Navigation Surgical Guidance System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (L1-S1).	The EXCELSIUS GPS™ is intended for use as an aid for precisely locating anatomical structures and for the spatial 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. The system is indicated for the placement of spinal and orthopedic bone screws.
Principles of Operation	- Intraoperative/ preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments - Guidance of instruments	- Intraoperative/ preoperative images - Patient registration - Surgical planning - Real-time tracking of navigated instruments - Guidance of instruments
Input Images	3D Intraoperative images	3D Pre-operative images 3D Intraoperative images 2D Intraoperative images
Integrated Planning Software	PNSGS Planning and Navigation Software	Excelsius™ GPS Planning and Navigation Software
Save/load Planning	Yes	Yes
Image Merging	No	Yes
Trajectory planning parameters	Entry point, target point, length of the instrument, diameter	Entry point, target point, length of the instrument, diameter
Localization method	Optical System (infrared Camera)	Optical System (infrared Camera)
Camera system	Monocular	Stereo
Image-guided	Yes	Yes
Controller	Manual macro adjustments Force-controlled movement of Targeting platform	Force-controlled movement allowing robotic arm positioning
Patient Registration Method	Registration fixture in place during 3D intraoperative images	Registration fixture during 3D intraoperative images. Fluoroscopic merge to pre-op CT Registration fixture in place during fluoroscopy
Accuracy verification on anatomical landmarks	Yes	Yes
Real time display of instrument position	Yes	Yes
Instrument Guidance	Trajectory and location set by Targeting platform. Instruments are manually	Trajectory and location set by the robotic arm. Instruments are manually positioned by the

Feature	Practical Navigation Surgical Guidance System (Subject Device)	Globus Medical, Inc. Excelsius GPS (K171651)
	positioned by the surgeon through the Guide Tube on the Targeting Platform.	surgeon through the Guide Tube on the robotic arm.
Patient fixation	Tracking Camera is fixed to OR table and to the patient's iliac crest.	Dynamic reference system is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc.

8. Performance Data

Practical Navigation Surgical Guidance System was tested in accordance with the design requirements. Testing included the following:

- Non-clinical system, software, and instrument verification and validation.
- Cadaver and simulated-use testing under clinically relevant scenarios.
- ASTM F2554-10 *Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems*.
- ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Testing.

9. Conclusion

Based on the indications for use, technological characteristics, performance results, and comparison to the predicates, the Practical Navigation Surgical Guidance System has been shown to be substantially equivalent to the predicate devices identified in this submission and does not present any new issues of safety or effectiveness.