December 23, 2021

Integrity Implants Inc.
% Roshana Ahmed
Sr. Regulatory Specialist
TELOS Partners, LLC
571 Christina Lake Drive
Lakeland, Florida 33813

Re: K212088
Trade/Device Name: Integrity Implants Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 22, 2021
Received: November 24, 2021

Dear Roshana Ahmed:

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

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)*
K212088

Device Name

Integrity Implants Navigated Instruments

Indications for Use *(Describe)*

Integrity Implants Navigated Instruments are intended to be used during the preparation and placement of Integrity Implants spinal implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures.

Integrity Implants Navigated Instruments are specifically designed for use with Medtronic's 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 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. Submitter

Integrity Implants Inc.
354 Hiatt Drive
Palm Beach Gardens, FL 33418
Phone: 561-529-3861

Contact Person: Roshana Ahmed, M.A., RAC, Senior Regulatory Specialist, Telos Partners LLC
Secondary Contact Person: Lauren Kamer, Sr. Director of Reg Affairs, Integrity Implants Inc.

Date Prepared: December 22, 2021

II. Device

Device Proprietary Name:	Integrity Implants Navigated Instruments
Common or Usual Name:	Navigation Instruments
Classification Name:	Stereotaxic Instruments
Regulation Number:	21 CFR 882.4560
Product Code:	OLO
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate devices:

- Navigated CD Horizon Solera Screwdriver/Taps, K140454, Medtronic Sofamor Danek USA, Inc.

The following secondary predicate devices are cited within the submission:

- LineSider® Spinal System, K190360, Integrity Implants, Inc.
- LineSider® Spinal System, K203367, Integrity Implants, Inc.

IV. Device Description

The Integrity Implants Navigated Instruments include non-sterile screw drivers, cannulated and solid taps (4.0 – 10.5 mm), probes, and awls designed to function with the Medtronic StealthStation® System and NavLock® Tracker. The subject devices are for use with the Integrity Implants LineSider® Spinal System (K190360 and K203367). The instruments are manufactured from stainless steel and Radel.

V. Indications for Use

Integrity Implants Navigated Instruments are intended to be used during the preparation and placement of Integrity Implants spinal implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures.

Integrity Implants Navigated Instruments are specifically designed for use with Medtronic's 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 vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

VI. Comparison of Technological Characteristics

The navigated instruments are identical to the predicate navigated instruments in that they are both intended to be used during the preparation and placement of implants during spinal surgery, incorporate the same design features to ensure navigation and compatibility with the Medtronic StealthStation® System and NavLock® Tracker to precisely locate anatomical structures, are made from the same materials, and utilize the same sterilization methods. The devices are equivalent in dimensions to the predicate instruments.

The table below compare the indications for use and key technological features between the subject and predicate device.

Parameter	**Subject Device**	**Navigated CD Horizon Solera Screwdriver/Taps (K140454)**	**Analysis**
Manufacturer	Integrity Implants Inc.	Medtronic Sofamor Danek USA, Inc.	N/A
Indications for Use	Integrity Implants Navigated Instruments are intended to be used during the preparation and placement of Integrity Implants spinal implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Integrity Implants Navigated Instruments are specifically	Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Medtronic Navigated Reusable Instruments are	Substantially Equivalent

Parameter		Subject Device	Navigated CD Horizon Solera Screwdriver/Taps (K140454)	Analysis
		designed for use with Medtronic's 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 vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.	specifically designed for use with the 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. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.	
Probes and Awls	**Tip Geometry**	Trocar tip (Awl) Tapered Straight Probe Duckbilled Straight Probe	Trocar tip (Awl), Tapered (aka Thoracic) Probe Duckbilled (aka Lumber) Probe	Substantially equivalent
	Materials	Stainless Steel	Stainless Steel	
Taps	**Diameter**	4.0 – 8.5 mm	3.75 – 8.5 mm	Substantially equivalent
	Design	Solid or cannulated Dual Lead, Quad Lead	Solid or cannulated Dual Lead	
	Materials	Stainless Steel	Stainless Steel	
Drivers	**Diameter**	5.5 – 6.0 mm	5.5 – 6.0 mm	Substantially equivalent
	Materials	Stainless Steel and Radel	Stainless Steel	Substantially equivalent
Sterilization		Non-Sterile	Non-Sterile	Substantially equivalent

VII. Performance Data

Performance testing of the subject devices, including accuracy testing in accordance with ASTM F2554-18, *Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems,* was completed to ensure the functionality and compatibility of the Integrity Implants Navigated Instruments with the Medtronic StealthStation® Surgical System and the NavLock® Tracker.

Registration testing was performed to ensure the instruments can be registered with the StealthStation System.

A dimensional analysis was conducted to demonstrate that the subject devices are substantially equivalent to the predicate devices.

Cleaning and sterilization validation data from K190360 were leveraged in support of the substantial equivalence determination.

VIII. Conclusion

The information provided above supports that the Integrity Implants Navigated Instruments are as safe and effective as the predicate device. Although minor differences in design and technology exist between the subject and predicate devices, the testing supports that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the Integrity Implants Navigated Instruments are substantially equivalent to the predicate device.