Innosys Co., Ltd.
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

June 14, 2024

Re: K241082
Trade/Device Name: INNOVERSE Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 19, 2024
Received: April 19, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.06.14 11:33:10 -04'00'

for

Colin O'Neill, MBE
Assistant Director
DHT6B: Division of Spinal 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241082

Device Name

INNOVERSE Navigation Instruments

Indications for Use *(Describe)*

INNOVERSE Navigation Instruments are intended to be used during the preparation and placement of INNOVERSE Spinal System implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in spinal procedures. These instruments are designed for use with the stereotactic navigation system Medtronic StealthStation™, 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 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.

510(K) SUMMARY

Submitter's Name:	Innosys Co., Ltd.
Submitter's Address:	20, Sandan-Ro 76beon-Gil(Rd) Uijeongbu-Si, South Korea 11781
Submitter's Telephone:	+82 31-860-6839
Contact Person:	Nathan Wright, MS, RAC Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	April 19, 2024
Trade or Proprietary Name:	INNOVERSE Navigation Instruments
Device Classification Name:	Orthopedic Steretaxic Instrument
Classification & Regulation #:	Class II per 21 CFR §882.4560
Product Code:	OLO
Classification Panel:	Restorative, Repair and Trauma Devices (DHT6C)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The INNOVERSE Navigation Instruments are reusable surgical instruments for use with the Medtronic® StealthStation™ Navigation System to assist surgeons in precisely locating anatomical structures in open or minimally invasive procedures for preparation and placement of pedicle screw implants.

The INNOVERSE Navigation Instruments include awls, probes, taps, and drivers and are to be used with the INNOVERSE Spinal System.

All instruments are made from Stainless Steel per ASTM F899. The INNOVERSE Navigation Instruments are not compatible with implants from other manufacturers and are designed for use only with Medtronic® StealthStation™ Navigation System hardware and software.

INDICATIONS FOR USE

INNOVERSE Navigation Instruments are intended to be used during the preparation and placement of INNOVERSE Spinal System implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in spinal procedures. These instruments are designed for use with the stereotactic navigation system Medtronic® StealthStation™, 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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
- Intended Use and Function
- Materials of manufacture
- Manufacturing and Biocompatibility

- Sterilization and Packaging

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K223494	Navigated Reusable Instruments for use with StealthStation™ and IPC™ Powerease™ Systems	Medtronic®	OLO	Primary
K233960	INNOVERSE Spinal System	Innosys Co., Ltd.	NKB	Reference

PERFORMANCE DATA

The INNOVERSE Navigation Instruments have been tested for positional accuracy per ASTM F2554-18, "Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems". The results of this non-clinical testing show that performance of the INNOVERSE Navigation Instruments is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and performance testing data lead to the conclusion that the INNOVERSE Navigation Instruments are substantially equivalent to the predicate devices.