July 23, 2025

Innovasis, Inc.
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K251073
Trade/Device Name: Innovasis Navigation Instruments (Vector G-E Navigation Instruments and the Excella G-E Navigation Instruments)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 20, 2025
Received: June 20, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shumaya Ali -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251073

Please provide the device trade name(s).

Innovasis Navigation Instruments (Vector G-E Navigation Instruments and the Excella G-E Navigation Instruments)

Please provide your Indications for Use below.

The Innovasis Navigation Instruments are intended to be used in the preparation and placement of Innovasis pedicle screws during non-cervical spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures for skeletally mature patients. These instruments are designed for use with the Globus ExcelsiusGPS 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K251073 510(K) SUMMARY

Submitter's Name:	Innovasis, Inc.
Submitter's Address:	614 E 3900 S Salt Lake City, Utah 84107
Submitter's Telephone:	801-261-2236
Contact Person:	Nathan Wright, MS, RAC Empirical Technologies 1-719-351-0248801-261-2236 nwright@empiricaltech.com
Date Summary was Prepared:	July 23, 2025
Trade or Proprietary Name:	Innovasis Navigation Instruments (Vector G-E Navigation Instruments and Excella G-E Navigation Instruments)
Device Classification Name:	Orthopedic Stereotaxic Instrument
Classification & Regulation #:	Class II per 21 CFR 882.4560
Product Code:	OLO
Classification Panel:	Division of Restorative, Repair, and Trauma Devices (DHT6C)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Innovasis Navigation Instruments (Vector G-E Navigation Instruments and the Excella G-E Navigation 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 ExcelsiusGPS® Robotic Navigation Platform to aid in implantation of the Innovasis pedicle screw system (Vector Pedicle Screw System and Excella Spinal System) implants. The instruments are manufactured from medical grade stainless steels and plastic.

INDICATIONS FOR USE

The Innovasis Navigation Instruments are intended to be used in the preparation and placement of Innovasis pedicle screws during non-cervical spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures for skeletally mature patients. These instruments are designed for use with the Globus ExcelsiusGPS 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.

TECHNOLOGICAL CHARACTERISTICS

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K171651	Excelsius GPS	Globus Medical Inc.	OLO	Primary
K250182	Innovasis Navigation Instruments	Innovasis, Inc.	OLO	Additional
K241276	Vector™ Pedicle Screw System	Innovasis, Inc.	NKB	Additional
K102248	Excella® Spinal System	Innovasis, Inc.	NKB	Additional

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

- Device design and dimensions
- Indications for use

- Materials of manufacture
- Principles of operation

	Innovasis Navigation Instruments (K251073)	Globus Medical ExcelsiusGPS (K171651)
Predicate Comparison and Purpose	The subject device only includes instruments (that prepare the surgical site and that implant the Innovasis pedicle screws into the patient bone) which are intended for use with the ExcelsiusGPS Robotic system hardware and software to assist the surgeon with instrument guidance. This 510(k) submission demonstrates substantial equivalence between the subject instruments and the predicate instruments only when the subject instruments are used in place of the Globus instruments because the subject instruments have equivalent critical dimensions and functionality with the ExcelsiusGPS System hardware and software.	
Indications for Use	The Innovasis Navigation Instruments are intended to be used in the preparation and placement of Innovasis pedicle screws during non-cervical spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures for skeletally mature patients. These instruments are designed for use with the Globus ExcelsiusGPS 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.	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.
Materials	Stainless Steel	Stainless Steel per ASTM F899
Sterility	Non-Sterile (End-user Sterilized)	Non-Sterile (End-user Sterilized)
Taps	Function To provide navigation array attachment and to tap the pedicle for screw placement.	Function To provide navigation array attachment and to tap the pedicle for screw placement.
Drivers	Function To provide navigation array attachment and to drive the screw into the pedicle. Driver Types Open, Reduction, and Minimally Invasive Drivers	Function To provide navigation array attachment and to drive the screw into the pedicle. Driver Types Open, Reduction, and Minimally Invasive Drivers
Driver Arrays	Function To provide for attachment of the spherical markers which the camera tracks.	Function To provide for attachment of the spherical markers which the camera tracks.

PERFORMANCE DATA

The Vector G-E Navigation Instruments and Excella G-E Navigation Instruments have been evaluated through an engineering analysis and geometric comparison to predicate devices to establish the safety and efficacy for accuracy performance. Biocompatibility evaluation of the instruments was leveraged from cited additional predicate devices by Innovasis, Inc. In addition, pass/fail verification testing demonstrated that the subject instruments adequately registered with the navigation system and appropriately fit within the guide tube of the end-effector. The results of this verification testing and engineering analysis show that the subject is substantially equivalent to the cleared predicate.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Innovasis Navigation Instruments (Vector G-E Navigation Instruments and the Excella G-E Navigation Instruments) are substantially equivalent to the predicate device.