May 2, 2023

Innovasis, Inc.
Michael Thomas
Regulatory Affairs Manager
614 E 3900 S
Salt Lake City, Utah 84107

Re: K223511
Trade/Device Name: Excella Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: [NOTE: Use date of most recent supplement]
Received: May 5, 2023

Dear Michael Thomas:

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 -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

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.

Submission Number *(if known)*

K223511

Device Name

Excella Navigation Instruments

Indications for Use *(Describe)*

The Excella® Navigation Instruments are intended to be used during the preparation and placement of Excella II®, Excella 3® & Excella MIS® screws during spinal surgery to assist the surgeon in locating anatomical structures in either open or percutaneous spinal procedures. The Excella Navigation Instruments are specifically designed for use with the Medtronic® StealthStation® System S8 and associated tracking arrays, 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 an acquired image (CT, MR, 2D/3D fluoroscopic image reconstruction) and/or an image-based model 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

Prepared on: 2022-11-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Innovasis, Inc.
Applicant Address	614 E 3900 S Salt Lake City UT 84107 United States
Applicant Contact Telephone	8012612236
Applicant Contact	Mr. Michael Thomas
Applicant Contact Email	mthomas@innovasis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Excella Navigation Instruments
Common Name	Stereotaxic instrument
Classification Name	Orthopedic Stereotaxic Instrument
Regulation Number	882.4560
Product Code	OLO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K140454	Medtronic Navigated CD Horizon Solera Screwdrivers and Taps	OLO

Device Description Summary

21 CFR 807.92(a)(4)

The Innovasis® Excella® Navigation Instruments are reusable instruments used for the preparation and insertion of Excella II®, Excella 3® & Excella MIS® screws, in either open or percutaneous procedures. These instruments are designed for navigated use with the Medtronic® StealthStation® System or as standalone, unnavigated instruments.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Excella® Navigation Instruments are intended to be used during the preparation and placement of Excella II®, Excella 3® & Excella MIS® screws during spinal surgery to assist the surgeon in locating anatomical structures in either open or percutaneous spinal procedures. The Excella Navigation Instruments are specifically designed for use with the Medtronic® StealthStation® System S8 and associated tracking arrays, 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 an acquired image (CT, MR, 2D/3D fluoroscopic image reconstruction) and/or an image-based model of the anatomy.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use are substantially equivalent. The subject Innovasis indications are a subset of the predicate indications (i.e., specifically spinal procedures).

Technological Comparison

21 CFR 807.92(a)(6)

The subject device has the same technological characteristics as the as the predicate device.
- Technology is substantially equivalent.
- Design is substantially equivalent.

- Size is substantially equivalent.
- Indications for use and intended use are substantially equivalent.
- Materials (biocompatibility profile) are substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Testing was conducted in accordance with "ASTM F2554-18 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems". The data shows all measurements were within specifications and comparable to the predicate product.

Navigation Accuracy Analysis: Confirmed navigated instrument accuracy.
Navigation Simulated Use: Confirmed navigation system functionality under expected use conditions.
CAD Model Evaluation: Verified that the CAD models are accurately reflected in the application software.
Implant/Instrument Mating Conditions: Verified that the instruments can be assembled with the appropriate devices according to their intended use.
Spine Tools Package Functional Testing: Verified that the Spine Tools package has met the required interface needs of the spine application software.