February 23, 2024

SI-BONE, Inc.
Daniel Cher
SVP, Clinical and Regulatory Affairs
471 El Camino Real, Suite 101
Santa Clara, California 94050

Re: K232800
Trade/Device Name: Navigation Tracking Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 23, 2024
Received: January 23, 2024

Dear Daniel Cher:

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,

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.

510(k) Number *(if known)*
K232800

Device Name
Navigation Tracking Instruments

Indications for Use *(Describe)*
The SI-BONE Trackers and Universal Pin Guide are intended to enable navigation of SI-BONE instrumentation during spinal surgical procedures that utilize Medtronic StealthStation™ Systems and Stealth™ Technology. The SI-BONE Trackers and Universal Pin Guide are specifically designed for use with the Medtronic 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for 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
Navigation Tracking Instruments

I. 510(k) SUBMITTER

SI-BONE, Inc.
471 El Camino Real, Suite 101
Santa Clara, CA 95050
Phone: 408-207-0700
Fax: 408-557-8312

Contact Person: Daniel Cher, SVP, Clinical and Regulatory Affairs

FDA Establishment Registration No.: 3007700286

Date Summary Prepared: February 22, 2024

II. DEVICE

Trade Name of Device:	Navigation Tracking Instruments
Classification Name:	Orthopedic Stereotaxic Instrument
Classification:	II
Regulation Number:	21 CFR 882.4560 Neurological Surgical Devices, Stereotaxic instrument Product Code
Product code:	OLO

III. PREDICATE DEVICE

Primary Predicate Device	**Manufacturer**	**510(k)#**	**Clearance Date**
Medtronic RIALTO™ SI Fusion System, Medtronic Reusable Instruments for Use with the IPC™ Powerease™ System, and Medtronic Navigated Manual Reusable Instruments for use with the StealthStation and IPC Powerease Systems	Medtronic	K161210	August 12, 2016
Additional Predicate Devices	**Manufacturer**	**510(k)#**	**Clearance Date**
Medtronic NavLock Trackers	Medtronic	K201327	June 18, 2020
IZI Medical Navigated Pedicle Access Kit	IZI Medical Products	K191012	August 7, 2019

IV. DEVICE DESCRIPTION

SI-BONE's Navigation Tracking Instruments ("Trackers") consist of fixed and rotating elements and a pin guide. The Trackers are reusable and made from aluminum and stainless steel. The Trackers

have fixed elements (posts) that support connection with reflective spheres. The Trackers can be securely attached to instruments used to place SI-BONE's implants during surgical procedures. SI-BONE's Fixed Trackers replicate the function of the Medtronic TeraTrackers. SI-BONE's Rotating Trackers replicate the function of Medtronic NavLock Trackers. SI-BONE's Universal Pin Guide replicates the function of the Medtronic Universal Drill Guide. An additional instrument is included with Fixed Trackers to allow the attachment and removal of the Fixed Trackers from the navigated instrument mounts.

SI-BONE Trackers can be used with the Medtronic StealthStation and Stealth Technology[1] to provide the surgeon access to dynamic, graphical representation of multi-plane 3D images (and 2D images) that indicate instrument and implant location in the body.

V. INDICATIONS FOR USE

The SI-BONE Trackers and Universal Pin Guide are intended to enable navigation of SI-BONE instrumentation during spinal surgical procedures that utilize Medtronic StealthStation™ Systems and Stealth™ Technology. The SI-BONE Trackers and Universal Pin Guide are specifically designed for use with the Medtronic 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

VI. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The Navigation Tracking Instruments are substantially equivalent to their predicates in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation as the predicate devices: the Medtronic RIALTO™ SI Fusion System, Medtronic Reusable Instruments for Use with the IPC™ Powerease™ System, and Medtronic Navigated Manual Reusable Instruments for use with the StealthStation and IPC Powerease Systems (most recently cleared in K161210) and the Medtronic NavLock Trackers (most recently cleared in K201327). Any differences between the Navigation Tracking Instruments and the predicate devices do not raise different or new questions of safety or effectiveness. Therefore, based on the intended use, indications for use, technological characteristics, and principles of operation, the Navigation Tracking Instruments are substantially equivalent to the predicate devices.

VII. PERFORMANCE DATA

SI-BONE performed comprehensive Design Verification and Validation Testing to demonstrate the safety and performance of SI-BONE's Navigation Tracking Instruments for its intended clinical use.

The following performance data were provided in support of the substantial equivalence determination.

[1] Stealth™ Technology — a combination of hardware, software, tracking algorithms, image data merging, and specialized instruments to help guide the surgeon during surgical procedures (ref: https://www.medtronic.com/us-en/healthcare-professionals/products/neurological/surgical-navigation-systems/stealthstation.html).

Biocompatibility Testing

Biocompatibility was assessed per ISO 10993-1. Biocompatibility testing is not required for the subject devices as raw materials and manufacturing materials and processes are identical to predicate devices.

Positional Testing

SI-BONE Navigation Tracking Instruments underwent and passed testing to verify registration, appropriate display of information and positional accuracy. All product specifications were met. Testing was performed per guidance in ASTM F2554-2018 - Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems.

Dimensional Verification

A one-to-one dimensional comparison was conducted to demonstrate substantially equivalent geometry that is critical to navigation accuracy.

VIII. CONCLUSION

The SI-BONE Navigation Tracking Instruments are substantially equivalent to both the primary and additional predicate instruments. The Navigation Tracking Instruments are substantially equivalent to its predicates in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation as the predicate devices: the Medtronic RIALTO™ SI Fusion System, Medtronic Reusable Instruments for Use with the IPC™ Powerease™ System, and Medtronic Navigated Manual Reusable Instruments for use with the StealthStation and IPC Powerease Systems (most recently cleared in K161210) and the Medtronic NavLock Trackers (most recently cleared in K201327) and IZI Medical's Navigated Pedicle Access Kit (most recently cleared in K191012). Any differences between the iFuse Navigation Tracking Instruments and the predicate devices do not raise any new or different questions of safety or effectiveness. Therefore, based on the intended use, indications for use, technological characteristics, and principles of operation, the Navigation Tracking Instruments are substantially equivalent to the predicate devices.