December 10, 2020

Navbit Pty Ltd
% Elizabeth O'Keeffe, PhD
Director of Regulatory Affairs
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K200376
Trade/Device Name: Navbit Sprint
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 11, 2020
Received: November 12, 2020

Dear Elizabeth O'Keeffe:

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,

For: 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: 06/30/2020

See *PRA Statement on last page.*

510(k) Number *(if known)*

K200376

Device Name

Navbit® Sprint

Indications for Use *(Describe)*

For Lateral Patient Registration:

The Navbit® Sprint System is a computer-controlled system intended to assist the surgeon in determining alignment in relation to reference axes during orthopedic surgical procedures. The Navbit® Sprint System facilitates the accurate positioning of implants, relative to these alignment axes.

The clinical setting and target population for the Navbit® Sprint System is that of a patient undergoing a Hip Arthroplasty surgical procedure by any approach with the patient in a lateral decubitus position.

The Navbit® Sprint System for lateral patient registration is indicated for use:

- in Hip Arthroplasty surgical procedures;
- with acetabular cups that are uncemented and allow for post-impaction correction;
- when post-impaction confirmatory measurement checks can be obtained.

For Supine Patient Registration:

The Navbit® Sprint System is a computer-controlled system intended to assist the surgeon in determining alignment in relation to reference axes during orthopedic surgical procedures. The Navbit® Sprint System facilitates the accurate positioning of implants, relative to these alignment axes.

The clinical setting and target population for the Navbit® Sprint System is that of a patient undergoing a Hip Arthroplasty surgical procedure by any approach with the patient in a supine position.

The Navbit® Sprint System for supine patient registration is indicated for use:

- in Hip Arthroplasty surgical procedures;
- with acetabular cups that are uncemented and allow for post-impaction correction;
- when post-impaction confirmatory measurement checks can be obtained.

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.

5. 510(k) Summary

510(k) Summary – Navbit® Sprint

Required	By section 21 CFR 807.92 (c)
Date Prepared	14th February, 2020
Owners Name	David Thomson QA/RA Manager
Submitter	Navbit Ltd Suite 1A, Level 1, 136 Willoughby Road Crows Nest 2065, Australia
Official Contact	Secure BioMed Evaluations Elizabeth O'Keeffe, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 (direct) 855-MED-DEV1 (office) Regulatory@SecureBME.com
Product Codes	OLO: Orthopedic Stereotaxic Instrument
Class	II
Classification Reference	21 CFR 882.4560
Common/Usual Name	Stereotaxic instrument.
Proprietary Name	Navbit® Sprint
Predicate Device(s)	OrthAlign Plus® System (**K172462**)
Reason for submission	New Device

5.1. Intended Use and Indications for Use:

For Lateral Patient Registration:

The Navbit® Sprint System is a computer-controlled system intended to assist the surgeon in determining alignment in relation to reference axes during orthopedic surgical procedures. The Navbit® Sprint System facilitates the accurate positioning of implants, relative to these alignment axes.

The clinical setting and target population for the Navbit® Sprint System is that of a patient undergoing a Hip Arthroplasty surgical procedure by any approach with the patient in a lateral decubitus position.

The Navbit® Sprint System for lateral patient registration is indicated for use:

- in Hip Arthroplasty surgical procedures;
- with acetabular cups that are uncemented and allow for post-impaction correction;
- when post-impaction confirmatory measurement checks can be obtained.

For Supine Patient Registration:

The Navbit® Sprint System is a computer-controlled system intended to assist the surgeon in determining alignment in relation to reference axes during orthopedic surgical procedures. The Navbit® Sprint System facilitates the accurate positioning of implants, relative to these alignment axes.

The clinical setting and target population for the Navbit® Sprint System is that of a patient undergoing a Hip Arthroplasty surgical procedure by any approach with the patient in a supine position.

The Navbit® Sprint System for supine patient registration is indicated for use:

- in Hip Arthroplasty surgical procedures;
- with acetabular cups that are uncemented and allow for post-impaction correction;
- when post-impaction confirmatory measurement checks can be obtained.

5.2. Device Description

The Navbit® Sprint System is a computer assisted surgical navigation system for use in hip arthroplasty procedures. The Navbit® Sprint System utilizes a palm-sized computer module containing sensors including rate gyroscopes and accelerometers to generate real time angular measurements (inclination and anteversion angles) used to guide acetabular cup implantation during orthopedic procedures.

During hip arthroplasty procedures, the Navbit® Sprint System assists the surgeon in registering the pelvic coordinate system and determining the inclination angle and the anteversion angle of the introducer/impactor relative to the registered pelvic coordinate system.

The device requires registration to be performed in one of two acceptable patient positions – supine and lateral, and alignment guidelines are provided for each. Any surgical approach that allows this registration to be performed is appropriate for use with the Navbit® Sprint.

The Navbit® Sprint System is provided terminally sterilized, single-use disposable.

5.3. Characteristics between predicate and new device

Trait	Subject Device: Navbit® Sprint	Predicate Device: OrthAlign Plus®	Comparison
510(k) number	**K200376**	**K172462** (prior clearance as **K130387**)	N/A
FDA Regulation	822.4560	822.4560	Equivalent
Product Code	OLO	OLO	Equivalent
Product Classification	Class II	Class II	Equivalent
Use	Prescription Use / Rx Only Part 21 CFR 801 Subpart D	Prescription Use / Rx Only Part 21 CFR 801 Subpart D	Equivalent
Indications for Use	The Navbit® Sprint System is a computer-controlled system intended to assist the surgeon in determining alignment in relation to reference axes during orthopedic surgical procedures. The Navbit® Sprint System facilitates the accurate positioning of implants, relative to these alignment axes. The clinical setting and target population for the Navbit® Sprint System is that of a patient undergoing a Hip Arthroplasty surgical procedure by any approach with the patient in a lateral decubitus /supine position. The Navbit® Sprint System for lateral/supine patient registration is indicated for use: • in Hip Arthroplasty surgical procedures; • with acetabular cups that are uncemented and allow for post-impaction correction; • when post-impaction confirmatory measurement checks can be obtained.	The OrthAlign Plus® System is a computer-controlled system intended to assist to the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The OrthAlign Plus® System facilitates the accurate positioning of implants, relative to these alignment axes. The system aids the surgeon in controlling leg length and offset discrepancies in Total Hip Arthroplasty. Ligament balancing is provided by the OrthAlign Plus® System in primary revision Total Knee Arthroplasty. Example orthopedic surgical procedures include but are not limited to: • Total Knee Arthroplasty • Total Hip Arthroplasty: Anterior/Posterior • Unicompartmental Knee Arthroplasty: Tibial transverse resection • Ligament Balancing	Equivalent *Navbit does not perform functions associated with knees, leg length and offset*

Trait	Subject Device: Navbit® Sprint	Predicate Device: OrthAlign Plus®	Comparison
Principle of Operation	Computer-assisted navigation system	Computer-assisted navigation system	Equivalent
Single Use	Yes	Yes	Equivalent
Location of Use	Hospital / Operating Theatre	Hospital / Operating Theatre	Equivalent
Biocompatibility	Per ISO 10993-1, Externally Communicating Device, Tissue/Bone/Dentin Communicating, with subsystems that have direct and potential indirect contact for a limited contact duration (< 24 hours)	Per ISO 10993-1, Externally Communicating Device, Tissue/Bone/Dentin Communicating, with subsystems that have direct and potential indirect contact for a limited contact duration (< 24 hours)	Equivalent
Materials	• Stainless Steel grades common to orthopedic surgical instruments • Polymer grades common to orthopedic surgical instruments • Internal electronics	• Stainless Steel grades common to orthopedic surgical instruments • Polymer grades common to orthopedic surgical instruments • Internal electronics	Equivalent
Control Mechanism	Computer generation of positional information, using inertial sensors, microcontroller, digital signal processor and physical positions of registration instruments.	Computer generation of positional information, using inertial sensors, microcontroller, digital signal processor and physical positions of registration instruments.	Equivalent
Operating Principles; Registration of Anatomy	Electronics attached to movable instruments, placed in specified procedural positions, on or in contact with bony anatomy, for recording sensor data.	Electronics attached to movable instruments, placed in specified procedural positions, on or in contact with bony anatomy, for recording sensor data.	Equivalent
Measurement and Navigation	• Computer derived values. • Accelerometer and rate gyroscope measurement of orientation of instrument.	• Computer derived values. • Accelerometer and rate gyroscope measurement of orientation of instrument. • Linear encoder reading of probe position (for distance to determine position).	Equivalent *Navbit does not support positional measurements*
Main System Components	• Single-use computer unit • Navigation and measurement software • Single Use instrument sets (provided with disposable kit)	• Single-use computer unit • Navigation and measurement software • Reusable instrument sets (provided as separate instrument set)	Equivalent
User Interface	Integrated graphical user interface, on an electronic unit that attaches to instrumentation	Integrated graphical user interface, on an electronic unit that attaches to instrumentation.	Equivalent
Energy Type	• Two internal IEC-FR03 (ANSI 24-LF) • Chemistry: Lithium/Iron Disulfide (Li/FeS2) • Voltage: 3V (series) • Storage Temp.: -40˚C to 60˚C • Operating Temp.: -40˚C to 60˚C	• One provided IEC-CR2, installed into Navigation Unit by user. • Chemistry: Lithium/Manganese Dioxide (Li/MnO2) • Voltage: 3V • Storage Temp.: -40˚C to 60˚C • Operating Temp.: -40˚C to 60˚C	Equivalent

Trait	Subject Device: Navbit® Sprint	Predicate Device: OrthAlign Plus®	Comparison
Sterilization	• Navigation unit: EO sterilization. • Instruments (Pins): EO sterilization.	• Navigation unit: EO sterilization. • Instruments: autoclave sterilization.	Equivalent *Navbit® Sprint Device and Bone Pins are supplied sterile*
Registration	Registration required using pins fixed to the hip.	Registration required using pins fixed to the hip.	Equivalent
Patient Interface *(i.e. Bone Pins)*	• Instrument fixation to pelvic bone with pins. • Pin diameter of 4.0 mm, pin length of 125.0 mm • 316L surgical Stainless Steel (ASTM 138)	• Instrument fixation to pelvic bone with pins and screws. • Pin diameter 5/32" (4.0 mm), pin length 110.0 mm. • 316L surgical Stainless Steel (ASTM 138)	Equivalent *Variations in pin length dictated by different interfacing equipment, equivalent patient/thread engagement*
Environmental specifications	Specified storage and operating environments for typical transport and surgical environments	Specified storage and operating environments for typical transport and surgical environments.	Equivalent

Table 1: Comparison between Predicate Device OrthAlign Plus® System (K172462) and Navbit® Sprint System

5.4. Substantial Equivalence

As a result of the Risk Analysis review and design input requirements, verification activities were performed on the Navbit® Sprint System. All tests confirmed the product met the predetermined acceptance criteria. This included testing against the FDA consensus standard, **ASTM F2554-18** *Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems*. Navbit has determined the Navbit® Sprint System to be as safe and effective as the predicate device [OrthAlign Plus® System (**K172462**)].

5.5. Performance Data

Device performance testing confirms that the Navbit® Sprint System can be used according to its intended use. The Navbit® Sprint System has been verified and validated according to Navbit procedures for product design and development. Performance testing addressed the functionality and surgical procedure workflows/steps as defined in the Navbit® Sprint user manual and demonstrates that the Navbit® Sprint System is as safe, as effective, and performs as well as the predicate device [OrthAlign Plus® System (**K172462**)].

5.6. Non-Clinical Testing

All non-clinical testing was performed to demonstrate the equivalence of the subject device, and all testing met the predetermined acceptance criteria.

Non-clinical testing included:

- Software verification and validation to ensure the integrity of the code and functionality including reliability of the software in various use sequences.

- System hardware verification/validation testing to ensure the Navbit® Sprint Device and its instruments meet their mechanical requirements.
- Instrumentation cleaning, sterilization and shipping validations or adoptions for the specified processes.
- System components biocompatibility assessment per **ISO 10993-1:2018**.
- System accuracy testing: bench testing with mechanical fixtures to verify angular measurement accuracy using **ASTM F2554-18**.
- Simulated use (cadaver) testing of the Navbit® Sprint System with an advising surgeon to validate that the system meets the requirements for user needs in a simulated use environment provides validation evidence that the product met the predetermined clinical pass/fail criteria.

5.7. Clinical Testing

No clinical trial required. Simulated use testing on cadavers performed.

5.8. Animal Studies

No animal studies were performed for the Navbit® Sprint system.

5.9. Conclusion

The Navbit® Sprint System is substantially equivalent the predicate device OrthAlign Plus® System (**K172462**). Testing against the FDA consensus performance standard (**ASTM F2554-18**) and clinical validation using cadaver models has demonstrated that the Navbit® Sprint is as safe and as effective as the predicate device.