July 30, 2026

Suite 201, National Innovation Centre
David Thomson
Navbit Pty Ltd
4 Cornwallis Street
South Eveleigh
Nsw, 2015 Australia
Australia

Re: K261410
Trade/Device Name: Navbit MARQ (PRD-001-SUP (Supine Registration Kit), PRD-001-LAT (Lateral Registration Kit))
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 30, 2026
Received: April 30, 2026

Dear David Thomson:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.	K261410

Please provide the device trade name(s).

Navbit MARQ (PRD-001-SUP (Supine Registration Kit), PRD-001-LAT (Lateral Registration Kit))

Please provide your Indications for Use below.

The Navbit MARQ 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 MARQ System facilitates the accurate positioning of implants, relative to these alignment axes.

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

The Navbit MARQ System 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

navbit.pty.ltd | info@navbit.com | +61 02 9209 4130
Suite 201, National Innovation Centre, 4 Cornwallis Street,
South Eveleigh, 2015, NSW, Australia

510(k) Summary - K261410

Navbit MARQ — 510(k) Summary prepared in accordance with 21 CFR 807.92

1. Submission Information

Field	Value
Submitter	Navbit Pty Ltd, Suite 201, National Innovation Centre, 4 Cornwallis Street, South Eveleigh, NSW 2015, Australia
Contact	David Geoffrey Thomson, Chief Regulatory & Commercial Risk Officer, dave.thomson@navbit.com, +61 433 482 325
Product Code	OLO: Stereotaxic Instrument
Class	II
Classification Reference	21 CFR 882.4560
Common/Usual Name	Stereotaxic instrument
Proprietary Name	Navbit MARQ
Predicate Device(s)	Navbit Sprint (K200376)
Reason for Submission	New Device

2. Intended Use and Indications for Use

For Lateral Patient Registration

The Navbit MARQ 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 MARQ System facilitates the accurate positioning of implants, relative to these alignment axes.

The clinical setting and target population for the Navbit MARQ 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 MARQ 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 MARQ 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 MARQ System facilitates the accurate positioning of implants, relative to these alignment axes.

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

The Navbit MARQ 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.

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3. Device Description

The Navbit MARQ System is a computer-assisted surgical navigation system for use in hip arthroplasty procedures. The system comprises three principal components:

(1) the MARQ Device, a battery-powered inertial navigation unit with a high-contrast OLED display, mechanical button, and Hall-effect sensor;

(2) the Bone Pin Assembly; and

(3) the Impactor Fitting Assembly.

The MARQ Device utilises a MEMS inertial measurement unit (IMU) containing accelerometers and gyroscopes to generate real-time angular measurements (inclination and anteversion angles) used to guide acetabular cup implantation. The device requires registration in one of two acceptable patient positions — supine and lateral — and alignment guidelines are provided for each. The Navbit MARQ System is provided terminally sterilised (EO), single-use disposable.

4. Substantial Equivalence Comparison

The device is substantially equivalent to the predicate Navbit Sprint (K200376). Both devices share the same fundamental technological characteristics: IMU-based inertial navigation with MEMS accelerometers and gyroscopes, bone-fixed reference frame registration, real-time angular measurement display, and confirmatory post-impaction measurement.

The MARQ incorporates design changes relative to the Sprint, including an integrated single bone pin assembly, an OLED display, a mechanical push button activation, revised battery configuration, and a refined mechanical housing. None of these changes raise new questions of safety or effectiveness, as demonstrated through the performance, biocompatibility, and electrical safety testing presented in this submission.

5. Performance Data and Non-Clinical Testing

Non-clinical testing included:

- Software verification and validation per IEC 62304 (Class B)
- System hardware verification/validation testing
- Sterilisation validation (EO) per ISO 11135 and shipping validation per ASTM D4169
- Biocompatibility assessment per ISO 10993-1
- Electrical safety and EMC testing per IEC 60601-1 and IEC 60601-1-2
- Summative usability study per IEC 62366-1
- System accuracy testing per ASTM F2554
- Simulated-use cadaver testing

All non-clinical testing met predetermined acceptance criteria, demonstrating equivalence of the MARQ to the predicate. The Navbit MARQ System demonstrated substantial equivalence to the Navbit Sprint in both system accuracy and simulated-use cadaver testing.

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6. Clinical and Animal Studies

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

No animal studies were performed for the Navbit MARQ System.

7. Conclusion

The Navbit MARQ System is substantially equivalent to the predicate device Navbit Sprint (K200376). All non-clinical testing — encompassing software, hardware, biocompatibility, electrical safety, sterilisation, usability, and performance — met acceptance criteria. Testing against the FDA-recognised consensus performance standard (ASTM F2554) and clinical validation using cadaver models has demonstrated that the Navbit MARQ is as safe and as effective as the predicate device for its intended use.