Navbit Pty Ltd
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

December 5, 0224

Re: K243447
Trade/Device Name: Rapid Surgical Plan (RSP-SW-001)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 6, 2024
Received: November 7, 2024

Dear Dave Yungvirt:

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,

Jessica Lamb
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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)*
K243447

Device Name
Navbit Rapid Surgical Plan

Indications for Use *(Describe)*

Navbit Rapid Surgical Plan is intended for pre-operative planning for primary total hip arthroplasty. Rapid Surgical Plan is intended to be used as a tool to assist the surgeon in the selection and positioning of components in primary total hip arthroplasty.

Rapid Surgical Plan is indicated for individuals undergoing primary hip surgery.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K243447

510(k) Owner	Navbit Pty Ltd Suite 201, National Innovation Centre, 4 Cornwallis Street, South Eveleigh 2015, Eveleigh, NSW, Australia Phone: +612 9209 4130
Contact Person	David Thomson Chief Regulatory Affairs and Commercial Risk Officer Email: dave.thomson@navbit.com Phone: +61(0)433482325
Date of Submission	5 Dec, 2024
Classification Reference	21 CFR 892.2050
Product Code	LLZ
Common/Usual name	Medical Image Management And Processing System
Trade/Proprietary Name	Navbit Rapid Surgical Plan®
Predicate Device(s)	RI.HIP MODELER (K212040)
Reason for Submission	New Device

Indications for Use

Navbit Rapid Surgical Plan is intended for pre-operative planning for primary total hip arthroplasty. Rapid Surgical Plan is intended to be used as a tool to assist the surgeon in the selection and positioning of components in primary total hip arthroplasty.

Rapid Surgical Plan is indicated for individuals undergoing primary hip surgery.

Device Description

The Navbit Rapid Surgical Plan is a non-invasive total hip arthroplasty planning software. It is software as a medical device (SaMD) which provides pre-operative planning for acetabular component orientation for orthopaedic surgeons. The software provides a recommended cup target intended to reduce impingement based on each patient's spinopelvic mobility. The ultimate decision to use the cup target recommended by Navbit is the surgeon's based on their clinical judgement.

Discussion of Similarities and Differences

Navbit RSP is substantially equivalent to its predicate device. The table below compares Navbit RSP to the selected predicate device, RI.HIP MODELER. The predicate device information has been sourced from the 510k premarket notification (K212040). An assessment of the substantially equivalent differences is included after the table.

Characteristic	Subject Device Navbit RSP	Predicate Device RI.HIP Modeler (K212040)
Intended Use/Indications for Use (same)	Navbit Rapid Surgical Plan is intended for pre-operative planning for primary total hip arthroplasty. Rapid Surgical Plan is intended to be used as a tool to assist the surgeon in the selection and positioning of components in primary total hip arthroplasty. Rapid Surgical Plan is indicated for individuals undergoing primary hip surgery	RI.HIP MODELER is intended for pre-operative planning for primary total hip arthroplasty. RI.HIP MODELER is intended to be used as a tool to assist the surgeon in the selection and positioning of components in primary total hip arthroplasty. RI.HIP MODELER is indicated for individuals undergoing primary hip surgery.
Classification and regulation (same)	LLZ 892.2050	LLZ 892.2050
Main system components (same)	Standalone software	Standalone software
Operational environment (same)	Navbit RSP report is intended to be used by in a clinical setting by a qualified surgeon.	RI.HIP MODELER is intended to be used in a clinical setting by a qualified surgeon.
Imaging requirements	Weightbearing AP, lateral standing, lateral relaxed seated and lateral flexed seated	Weightbearing lateral standing and lateral relaxed seated

(substantially equivalent)[1]		
Image acquisition, source and modalities features (substantially equivalent)[2]	X-ray images are acquired externally to the system by healthcare professionals following an imaging protocol to produce DICOM files. The DICOM files are uploaded directly to the RSP and displayed in PNG format for planning and visualization purposes. The RSP itself does not acquire images directly.	X-ray images are acquired externally to the system by healthcare professionals following an imaging protocol to produce DICOM files. These images are made available in RI.HIP MODELLER by downloading from Brainlab Quentry, or via an iPad camera roll, or iPad camera and are displayed in PNG format for planning and visualization purposes. The RI.HIP MODELLER itself does not acquire images directly.
Image Types Used (same)	PNG Images	PNG Images
Measurements and tools (substantially equivalent)[3]	Navbit RSP uses qualified surgical planning engineers to perform clinically relevant anatomical measurements that are based on supporting literature. Measurements are achieved using annotation tools that facilitate point placement, including lines and circles. The measurements include angles and linear measurements.	RI.HIP MODELER allows the surgeon to perform clinically relevant anatomical measurements that are based on supporting literature. Measurements are achieved using annotation tools that facilitate point placement, including lines. The measurements include angles.
Primary device function (substantially equivalent)[4]	Navbit RSP uses stand-alone software for computer assisted surgical planning. The primary function of the software is to provide a baseline cup orientation recommendation intended to reduce incidences of implant impingement based on inclination/anteversion and spinopelvic mobility.	RI.HIP MODELER uses stand-alone software for computer assisted surgical planning. The primary function of the software is to provide a baseline cup orientation recommendation intended to reduce incidences of implant impingement based on inclination/anteversion and implant specifications, and stem anteversion.

Clinical testing (same)	Non-clinical testing, which included clinical measurement accuracy testing, sufficiently demonstrated substantial equivalence in safety and effectiveness. No clinical testing required.	Non-clinical testing sufficiently demonstrated substantial equivalence in safety and effectiveness. No clinical testing required.

[1]*Imaging Requirements*

Navbit RSP requires 2 additional x-rays: weightbearing AP and flexed-seated. Weightbearing AP x-rays are standard practice in THA. The flexed-seated x-ray has been included based on the results of the literature review which identify its importance and use in identifying patients at risk of post-operative complications. The risks associated with radiation exposure from additional x-rays have been assessed in risk management activities. There are no new questions of safety or effectiveness due to the difference in imaging requirements. The imaging requirements are substantially equivalent to the requirements for the predicate device.

[2]*Image acquisition, source and modalities features*

Both the predicate device and the RSP utilise PNG images for landmarking in surgical planning. The RSP accepts PNG images that are uploaded via a DICOM modality, while the predicate device can receive PNG images through a broader range of methods, including the iPad Camera Roll, iPad Camera, and Brainlab Quentry, the latter being a DICOM modality.

Although the predicate device relies on Brainlab Quentry as an intermediate system to receive DICOM files, the RSP achieves the same functionality by allowing DICOM files to be downloaded from any third-party system and then uploaded into the RSP. Since DICOM is a standardised format, and both methods involve extracting a DICOM file from one system and uploading it into another, these approaches are considered substantially equivalent.

The RSP does not include iPad Camera Roll and iPad Camera as input methods, as no clinical need for these was identified. The iPad Camera Roll and Camera are used to capture images of a source image displayed on a screen, which would result in image quality that is equal to or lower than the original DICOM image. Therefore, the absence of a camera-based input does not introduce any new concerns regarding the safety and effectiveness of the RSP.

[3]*Measurements and Tools*

Both systems utilise annotation tools that allow users to place points, which define basic geometries such as lines and circles. These geometries are then used to perform simple measurements like angles. Unlike the predicate, the RSP additionally uses these geometries to perform length measurements, however this is also a simple measurement. The predicate does not use circle annotation tools. However, this functionality is equivalent in both systems as the circle annotation tool is a means of performing point placement.

Additionally, both systems use this user-driven annotation capability to landmark clinically relevant features on radiographs for the purpose of obtaining measurements. The annotated clinical features are based on established clinical definitions from the literature, which is equivalent across both systems.

The primary difference lies in the user performing the annotations: the predicate device is operated by surgeons, while the RSP is used by qualified planning technicians. To ensure equivalence, the planning technicians undergo performance testing against a reference dataset that has been landmarked by surgeons. This testing demonstrates that the performance of the planning technicians is equivalent to that of the surgeons for the scope of the landmarking tasks involved. Given that the performance of both groups is validated to be equivalent, this difference in user type does not introduce any new concerns regarding the safety or effectiveness of the RSP.

[4]Primary Device Function

The primary device function is substantially equivalent between the subject device and the predicate device. Both devices provide a recommended inclination/anteversion cup targets based on spinopelvic mobility. Navbit RSP provides additional spinopelvic analysis from the inclusion of the flexed-seated x-ray, however this does not contribute to the cup target recommendation and does not raise new questions of safety or effectiveness.

Principles of Operation

Navbit RSP is substantially equivalent to RI.HIP Modeler in principles of operations. Spinopelvic mobility of THA patients is assessed from standing and sitting x-rays. Navbit RSP uses an algorithm based on clinical recommendations for spinopelvic mobility to provide cup target recommendations. Similarly, RI.HIP Modeler uses an algorithm based on spinopelvic mobility classifications and hip kinematics in literature to recommend cup targets.

The RSP pre-operative planning process is conducted by trained planning technicians whereas RI.HIP Modeler analysis is conducted by surgeons. User validation showed that RSP planning technicians can conduct analyses that are as accurate as surgeon analyses. There are no new questions of safety or effectiveness due to the difference in pre-operative planning users as the processes involved in operation have been verified and validated for accuracy. Orthopaedic surgeons are the end users for both devices.

Technological Characteristics

- The subject and predicate device both recommend acetabular cup placement based on spinopelvic mobility classification.
- Both devices use functional lateral 2D x-rays to assess Spinopelvic mobility. Navbit RSP uses one extra x-ray (lateral flexed-seated x-ray).
- Rapid Surgical Plan analysis is performed by trained planning technicians. RI.HIP Modeler analysis is performed by surgeons.
- Rapid Surgical Plan is a web application and RI.HIP Modeler is an iPad application. Both devices are stand-alone software.

There are no new concerns for safety or effectiveness due to the difference in technological characteristics because Rapid Surgical Plan was designed to meet its intended use with the technological characteristics within the web-based software. Verification and Validation from Testing confirms that the Rapid Surgical Plan is safe and effective and meets its intended use. Validation Testing confirms that users of the Rapid Surgical Plan software were able to successfully and accurately perform analysis in a safe and effective way in the intended use environment.

User Interface

Navbit RSP is a standalone software that is intended to be installed on any computer. The predicate device is standalone software that can be installed on an iPad. The subject device software was verified and validated to ensure specifications were met. User validation showed that users can use the RSP safely and effectively on a computer to plan for total hip arthroplasty procedures. There are no new questions of safety or effectiveness due to the different interface as the design of Navbit RSP was specific to the intended interface and allows the device to perform its intended use.

Non-Clinical Testing (Bench)

The Rapid Surgical Plan (RSP) underwent extensive design verification and validation to confirm that it meets all design requirements and is as safe and effective as the predicate device. Comprehensive performance testing validated that the device fulfills the necessary design inputs. The performance data included:

- **Software Verification Testing**: Conducted software integration and workflow assessments in compliance with IEC 62304: Medical Device Software—Software Life Cycle Processes. Documentation aligns with the FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- **Clinical Measurement Accuracy Evaluation**: Used representative patient images to compare RSP outputs against a ground truth data set established by surgeons. Testing confirmed that the device achieves the required accuracy in clinical measurements.
- **Device Measurement Accuracy Evaluation**: Used test patterns to assess the non-clinical measurement accuracy of the RSP. Testing confirmed that the device achieves the required non-clinical measurement accuracy, with limits defined as follows:
    - Linear measurements: ±0.1mm with at least 95% confidence
    - Angular measurements: ±0.3° with at least 95% confidence
    - Ratio measurements: ±0.1 with at least 95% confidence
- **Usability Engineering Validation**: Demonstrated that representative users can safely and effectively operate the RSP in a simulated clinical environment.

No human clinical testing was necessary to establish the safety and effectiveness of the Rapid Surgical Plan.

Conclusion

Navbit RSP has a similar intended use, technological characteristics, principles of operations and primary device function as its predicate, RI.HIP MODELER (K212040). The primary difference between the devices is that Navbit RSP measurements are performed by trained planning technicians while RI.HIP MODELER measurements are performed by surgeons. User validation showed that RSP planning technicians can conduct analyses that are as accurate as

surgeon analyses. Navbit RSP report is intended to be used by in a clinical setting by a qualified surgeon. The differences do not raise any new questions of safety or effectiveness.

The results of verification and validation activities demonstrate that there are no issues of safety and performance and that the Navbit RSP satisfies its intended use. The information presented in this 510(k) premarket notification demonstrate that Navbit RSP is as safe and effective as the predicate device RI.HIP MODELER (K212040). Navbit RSP is substantially equivalent to the predicate device.