



July 14, 2019

Synaptive Medical Inc.
Maham Ansari
Director of Regulatory Affairs
555 Richmond Street West, Suite 800
Toronto, ON M5V 3B1

Re: K183325
Trade/Device Name: Modus Nav
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: June 12, 2019
Received: June 14, 2019

Dear Maham Ansari:

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,

Matthew Krueger
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K183325

Device Name

Modus Nav 1.7

Indications for Use (Describe)

Modus Nav is intended as a planning and intraoperative guidance system to enable open and percutaneous computer assisted surgery. The system is indicated for medical conditions requiring neurosurgical cranial procedures where the use of computer assisted planning and surgery may be appropriate. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified. The user should consult the "Accuracy Characterization" section of the User Manual to assess if the accuracy of the system is suitable for their needs.

The system hardware and software should be used only by qualified medical professionals who are trained in performing surgery and are familiar with image-guided surgical systems.

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.

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510(k) Summary

[As required by 21 CFR 807.92(c)]

Manufacturer: Synaptive Medical Inc.
Address: 555 Richmond Street West, Suite 800
 Toronto, ON M5V 3B1
 Canada
Establishment Registration: 3012075008

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Date Prepared: 15 November 2018

Device Proprietary Name: Modus Nav
Device Common or Usual Name: Neurological Stereotaxic Instrument
Classification Panel: Neurology
Product Code: HAW
Regulation Number: 21 CFR 882.4560
Regulation Class: II
Regulation Description: Stereotaxic Instrument

Predicate Devices:

Substantial equivalence is claimed to the following device:

Trade name	Manufacturer	510(k) Number	Date Cleared
BrightMatter Guide with Surface Trace Registration	Synaptive Medical Inc.	K153281	March 30, 2016

Device Description

The subject device, Modus Nav, is a modified version of its predicate, BrightMatter Guide with SurfaceTrace Registration. The system is a surgical planning and image guided surgical system that enables open or percutaneous computer-assisted cranial surgery. The system uses optical 3D tracking technology to display the location and orientation of tracked (also known as navigated) surgical instruments relative to the pre-operative scan images of the patient. The system consists of a software application installed on a computer, tracked surgical instruments, and accessories to enable the tracking of those instruments.

The planning functionality of the device is provided by an already cleared device called BrightMatter Plan 1.6.0 (K180394). The remaining functionality of the system can be broadly grouped into data preparation, registration and visualization of surgical tools. Data preparation and registration is performed during the initial stages of a surgical procedure and visualization of the tools is performed as needed during the surgical procedure.

General use of the system as an image guided surgical tool is composed of the following key steps:

- Equipment setup
- Plan selection and data preparation
- Patient registration
- Tool localization and visualization

An optical Tracking Camera provides the position and orientation of the tools with respect to the tracking origin. The navigated surgical tools are tracked using single-use passive reflective markers (K033621) that are attached to the surgical tools prior to each surgical procedure. An external display can be used by the surgical staff if needed, given that the Tracking Camera mounted on a cart maintains a line of sight between the Cranial Reference and the Tracked Surgical Tools. Both the User Cart (also known as Navigation Cart) and Auxiliary Carts are placed outside the sterile field.

The primary purpose of this 510(k) submission is to introduce new navigated tools such as the Short Pointer, Shunt Stylet, and the corresponding Calibration Device. It also introduces new software features to support the navigation of these tools, the ability to navigate with Synaptive's Trackable Suction tools, and minor workflow improvements to facilitate the surgical procedure.

Indications for Use

Modus Nav is intended as a planning and intraoperative guidance system to enable open and percutaneous computer assisted surgery. The system is indicated for medical conditions requiring neurosurgical cranial procedures where the use of computer assisted planning and surgery may be appropriate. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified. The user should consult the "Accuracy Characterization" section of the User Manual to assess if the accuracy of the system is suitable for their needs.

The system hardware and software should be used only by qualified medical professionals who are trained in performing surgery and are familiar with image-guided surgical systems.

Summary of Technological Comparisons

Modus Nav is an enhanced implementation of BrightMatter Guide with Surface Trace Registration, its previously FDA-cleared version. The primary function of both

devices is to track surgical instruments using an optical 3D tracking system and to show the location and orientation of these instruments relative to the pre-operative scan images of the patient during cranial procedures. The primary difference between Modus Nav and the predicate device is enhanced functionality through the introduction of new hardware involving tracked instruments, and minor workflow improvements.

Main advantages compared to the predicate device are:

- Minor improvements to usability introduced as a result of user acceptance testing, human factors testing and field feedback.
- Ability to track new instrumentation for enhanced functionality.

There are no known disadvantages.

Modus Nav remains substantially unchanged from the predicate with respect to its intended use and performance claims.

Nonclinical Performance Testing

Verification and validation testing has been conducted on the Modus Nav system to ensure the safety and effectiveness of the device to perform in accordance to its intended use. The following table provides a summary of the testing performed on the Modus Nav system.

Type	Activity	Description of Activity	Documentation Results
Software verification testing (system, sub-system, functional block, and compatibility testing)	Functional verification of integrated software system	Test of software application based on functional blocks and test cases developed to verify software requirements specifications (SRS) items. This activity was repeated in its entirety in this submission.	Verified acceptance criteria for all SRS items have been met.
	Testing of resolved anomalies	Testing of anomalies present in previously released versions of the device that have been resolved in the Modus Nav release.	Previous errors were tested and verified to no longer occur.

Type	Activity	Description of Activity	Documentation Results
Algorithm pipeline verification	Performance verification	Automated performance verification of the core data processing facility of the software (known as 'algorithm pipeline'). Uses known data sets and expert review of output generated by the pipeline at various stages of processing.	Performance verified using known data sets or 'truth data sets' to evaluate image processing pipeline and its outputs.
System Requirements Verification	Biocompatibility	See section below.	Testing passed all acceptance criteria.
	Cleaning Validation	External testing to validate cleaning instructions for reusable tools as per ISO 15883-1.	
	Sterilization Validation	External testing to validate sterilization parameters for reusable tools per AAMI TIR12, AAMI TIR30, ANSI AAMI ISO 17665-1, ANSI AAMI ISO TIR17665-2.	
	Medical Electrical System Safety	External testing against the requirements of ANSI AAMI IEC ES60601-1 to verify electrical and mechanical safety of the system.	
	Electromagnetic Compatibility	External testing against the requirements of IEC 60601-1-2 to verify that the system operates within safe limits of emission and interference requirements.	

Type	Activity	Description of Activity	Documentation Results
System Validation	User acceptance testing by intended user group	Testing of Modus Nav by intended user in a simulated use environment to validate customer needs and intended use.	All acceptance criteria met.
	Human Factors Validation	Testing of critical features by intended users to determine if device is safe and effective for intended users, uses and environments. Testing completed as per IEC ANSI AAMI 62366 and FDA Guidance: "Applying Human Factors and Usability Engineering to Medical Devices."	All acceptance criteria met.

Biocompatibility Testing

The following biocompatibility testing was also conducted on the material used for Modus Nav Tracked Tools, Shunt Stylet and Trackable Suction:

Test	Test Description	Results	Conclusions
Bacterial Endotoxins	Limulus amoebocyte lysate (LAL) in vitro test	Detected endotoxin is not more than 2.15 EU / device.	Non-endotoxic
Cytotoxicity	MEM Elution Cytotoxicity	Cell culture treated with samples exhibited slight reactivity (Grade 1).	Non-cytotoxic
Irritation/Intracutaneous toxicity	Intracutaneous Irritation Test (GLP – 2 Extracts)	None of the animals on study showed any clinical signs or dermal reactions.	Non-irritant
Sensitization	Guinea Pig Maximization	A negative sensitization incidence was	Non-sensitizing

Test	Test Description	Results	Conclusions
	Sensitization Test (GLP – 2 Extracts)	interpreted for all test animals. No abnormal clinical signs observed during test period.	
Material-mediated pyrogenicity	Materials Mediated Rabbit Pyrogen (GLP)	None of the rabbits administered with the test article extract had a temperature rise ~ 0.5 °C at the required observation time points.	Non-pyrogenic
Acute systemic toxicity	Acute Systemic Injection Test (GLP – 2 Extracts)	None of the animals on study were observed with abnormal clinical signs indicative of toxicity during the 72 hour test period.	Non-toxic
Hemocompatibility	Hemolysis (Extract Method)	The difference between the hemolytic indexes of the test article and the negative control was not higher than 0.49 percent for all tools.	Non-hemolytic
Extractables (Shunt Stylet only)	Toxicological evaluation of extractable chemicals	Gas Chromatography-Mass Spectrometry (GC-MS) and Inductively Coupled Plasma Mass Spectrometry (ICP-MS) met acceptance criteria.	Non-toxic

The Biocompatibility tests for the material used in both pointers were cleared in K160523.

The Biocompatibility test results indicate that Modus Nav can be considered safe and suitable for the intended use and is as safe and effective as the predicate device.

The following performance testing was also conducted on Modus Nav:

- *Accuracy Characterization:*
System accuracy was characterized using an accuracy measurement phantom of similar volume to an adult head. The values of the ground truth data from the accuracy phantom were obtained using a Coordinate Measurement Machine (CMM). Testing was conducted with all tracked tools calculating positional and angular error for both registration methods: Surface Trace Registration and Touch Point Registration. Testing confirmed that the Modus Nav system is accurate to within 2 mm and 2 degrees of the physical tip of the tracked tool. This is equivalent to the predicate device.
- *Latency Testing:*
The video latency of the subject device and the predicate device were compared and deemed to be equivalent.

All nonclinical testing described in this section successfully passed, demonstrating that the Modus Nav system is safe and effective for its intended use and substantially equivalent to its predicate device.

Clinical Testing

This technology is not new; therefore, a clinical study was not considered necessary prior to release. The substantial equivalence of the device is supported by the non-clinical testing.

Conclusion

Modus Nav has been shown through comparison and performance testing to be substantially equivalent to the identified predicate device. Any technological differences do not raise new questions of safety and effectiveness.