March 9, 2018

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

Re: K180394
Trade/Device Name: BrightMatter Plan 1.6.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 12, 2018
Received: February 13, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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 below.

510(k) Number *(if known)*
K180394

Device Name
BrightMatter Plan 1.6.0

Indications for Use *(Describe)*
BrightMatter Plan is indicated for:

• Viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, and image segmentation where the output can be used for image guided surgery.
• Planning and simulation of cranial surgical procedures.
• Reviewing of existing treatment plans.

Typical users of the software are medical professionals, including but not limited to surgeons and radiologists.

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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5. 510(k) Summary

[As required by 21 CFR 807.92]

Manufacturer:	Synaptive Medical Inc.
Address:	555 Richmond Street West, Suite 800 Toronto, ON M5V 3B1 Canada
Establishment Registration:	3012075008
Contact Name:	Ms. Maham Ansari, MS, RAC
Title:	Director, Regulatory Affairs
Phone Number:	+1 647 925 3435
Fax Number:	1 888 650 5230
Date Prepared:	12 February 2018
Device Proprietary Name:	BrightMatter Plan
Device Common or Usual Name:	BrightMatter Plan
Classification Name:	System, Image Processing, Radiological
Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Regulation Class:	II
Regulation Description:	Picture Archiving and Communications System

Predicate Devices

Substantial equivalence is claimed to the following device:

Trade name	Manufacturer	510(k) Number	Date Cleared
BrightMatter Planning Software 1.0	Synaptive Medical Inc.	K140337	June 02, 2014

Device Description

BrightMatter Plan is a treatment planning software that enables the user to view and process medical image data. The software is intended for pre-operative planning of neuro-surgical treatments based on image guided surgical systems. The planning software system provides the ability to visualize diagnostic images in 2D and 3D formats and fusion of image datasets. The software automatically segments the skull from the acquired image and generates diffusion tracts from Diffusion Tensor Imaging (DTI) data. The user can also manually annotate regions of interest, resulting in structures which can subsequently be visualized in 3D. A trained person can use the software to segment structures, define regions of interest and establish one or more trajectories.

The software, operated on a stand-alone computer workstation, is expected to be used by a Clinician in an office or home setting, in preparation for one of several possible surgical procedures. The end of the processing is a surgical plan which can be exported to a Picture Archiving and Communication Systems (PACS) for subsequent use in image guided surgery.

Indications for Use

BrightMatter Plan is indicated for:

- Viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, and image segmentation where the output can be used for image guided surgery.
- Planning and simulation of cranial surgical procedures.
- Reviewing of existing treatment plans.

Typical users of the software are medical professionals, including but not limited to surgeons and radiologists.

Summary of Technological Comparisons

BrightMatter Plan is an updated version of the predicate: its previously cleared version 1.0 (K140337). The subject device is substantially unchanged from the predicate with respect to indications and performance claims. The primary difference between the proposed and predicate devices is additional or altered functionality which improve the planning workflow or the user experience of the device.

Key differences and advantages compared to the predicate are:

1. BrightMatter Plan incorporates numerous improvements to usability.
2. The new software enables manual segmentation of tractography, in a manner similar to segmenting anatomical structures. This enables the planner to deliberately reduce the amount of information displayed during planning to the most useful elements.
3. The software exports a volumetric dataset, incorporating the planned target and engagement points. This enables more efficient translation of the plan to a PACS.
4. Removal of sulcal paths workflow stage since it cannot be utilized in commercially available navigation systems and was consequently not used in practice.

There are no known disadvantages with the proposed device in comparison to the predicate device.

The essential underlying technology used to process images is the same. The intended uses are equivalent. Direct comparison of major functionality showed largely identical results. Any changes introduced in the subject device do not raise new concerns of safety and effectiveness.

Non-Clinical Testing

The following bench (software verification) testing was conducted on BrightMatter Plan:

- Performance testing – algorithm pipeline verification; functional verification
- Unit level verification
- Integration verification
- Implementation requirements verification and system integration - release testing, compatibility testing, testing of resolved anomalies, and platform testing
- System requirements verification – review of traceability from systems requirements to implementation; labeling reviews.

Design Validation

Device (software) was tested by the intended user population using representative pre-operative images and evaluation of resulting plan for conformance to clinical expectations with production equivalent device. This was conducted to validate that the customer needs have been satisfied.

Effectiveness of risk control measures related to usability/human factors were also evaluated and validated via this activity.

Clinical Testing

This technology is not new; therefore, a clinical study was not considered necessary prior to release. Additionally, there was no clinical testing required to support the medical device as the indications for use are equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing.

Conclusion

BrightMatter Plan has been shown through comparison and testing to be substantially equivalent to the identified predicate device.