March 28, 2018

Medtech S.A.
Elise Lagacherie
RA/QA Manager
ZAC Eureka
900 rue du Mas de Verchant
34000 Montpellier, France

Re: K172444
Trade/Device Name: ROSA BRAIN (v3.0.0.5)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: February 22, 2018
Received: February 26, 2018

Dear Elise Lagacherie:

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 J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K172444

Device Name
ROSA BRAIN (v3.0.0.5)

Indications for Use *(Describe)*
The device is intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). The device is indicated for any neurosurgical procedure in which the use of stereotactic surgery may be appropriate.

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

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part §807.92.

I SUBMITTER

Medtech S.A.

ZAC Eurêka

900 rue du Mas de Verchant

34000 Montpellier, France

Tel +33 (0)4 67 10 77 40

Fax +33 (0)4 67 59 74 18

Contact Person :

Serge Tabet,

Quality & Regulatory Affairs Manager-Zimmer Biomet Robotics

serge.tabet@zimmerbiomet.com

Dated prepared: August 7, 2017

II DEVICE

Name of Device: **ROSA BRAIN** (v3.0.0.5)

Common Name: Computer-assisted surgical device

Classification Name: Stereotaxic Instrument (21CFR 882.4560)

Classification Panel: Neurology

Regulatory Class: II

Product Code: HAW

510k #: K172444

III PREDICATE DEVICE

ROSA BRAIN (v3.0.0.0), manufactured by Medtech S.A., K151359, cleared December 19, 2015

IV DEVICE DESCRIPTION

The ROSA BRAIN device is a robotized platform providing guidance of any neurosurgical instruments compatible with the diameter of the adaptors supplied by Medtech (for example, a biopsy needle).

The device is composed of a compact robotic arm and a touch screen mounted on a robot stand. Different types of instruments may be attached to the end of the robot arm and changed according to the requirements of the procedure to be completed.

The touch screen ensures the communication between the device and its user by indicating the actions to be done as well as by offering various commands.

ROSA BRAIN is an image-guided device that assists the surgeon in planning the position of instruments or implants on preoperative or intraoperative images. It provides a stable, accurate and reproducible mechanical guidance in accordance with the planning.

An image acquisition of the patient's head (MRI / CT images) is performed prior to surgery and loaded into the device.

In the preoperative phase, the surgeon carries out the surgical planning on the patient images using the device software. The desired surgical parameters for positioning of the surgical instruments are defined (for example: target point, entry point and instrument length).

During surgery, the device provides accurate and rigid guidance of the required instrument according to the previously completed planning.

The optical distance sensor used with the ROSA BRAIN is susceptible to Electrostatic Discharge (ESD).

The ROSA BRAIN device is intended to be used with anti-static sterile drapes which are designed for the device and listed in the list of compatible devices. The anti-static sterile drapes are mitigations to ROSA Brain device ESD immunity.

V INDICATIONS FOR USE

The device is intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). The device is indicated for any neurosurgical procedure in which the use of stereotactic surgery may be appropriate.

VI COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device	ROSA BRAIN 3.0.0.0 (K151359)	ROSA BRAIN 3.0.0.5 (submission subject)

Device	ROSA BRAIN 3.0.0.0 (K151359)	ROSA BRAIN 3.0.0.5 (submission subject)
Indications for use	Intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). The device is indicated for any neurosurgical procedure in which the use of stereotactic surgery may be appropriate.	Identical
Where used	Neurosurgical operating room	Identical
User	Neurosurgeon	Identical
General device description	Computer controlled electromechanical 6-axis multi-jointed arm	Identical
Principle of operation	• Preoperative images • Surgical planning • Patient registration • Guidance of instruments	Identical
	Preoperative images & surgical planning	
Preoperative images	3D MRI / CT	Identical
DICOM compliance	DICOM 3.0	Identical
Multimodality fusion	Yes (MRI/CT)	Identical
Planning software	ROSANNA BRAIN (v3.0.0.0) (product version)(Medtech)	ROSANNA BRAIN (v3.0.0.5) (product version) (Medtech) Justification: Upgraded version.
Integrated planning software	Yes	Identical
Define regions of interest (ROI)	Yes	Identical
Trajectory definition (stereotactic module)	Parameters for planning trajectories: entry point, target point, instrument length, diameter, name, color	Identical
Trajectory definition (endoscopy module)	Parameters for planning trajectories: entry point, target point, instrument length, diameter, name, security radius (10mm by default), security aperture (10° by default)	Identical
Save/load planning	Yes	Identical
	Patient registration	
Localization means	Robot arm absolute encoders	Identical

Device	ROSA BRAIN 3.0.0.0 (K151359)	ROSA BRAIN 3.0.0.5 (submission subject)
Controller	Axis controller for each joint Kinematic transformation between the Cartesian space and joint space Supervisor module	Identical
Registration methods	• Fiducial markers • Optical registration device • Stereotactic frame (fiducials mounted on the frame)	Identical
Fiducial markers registration with pointer probe	Yes	Identical
Optical registration with laser telemeter	Yes	Identical
Laser class for optical registration	2 (complies with 21 CFR 1040.10)	Identical
Cooperative movement	Yes	Identical
Accuracy verification on anatomical landmarks	Yes (navigation probe)	Identical
	Instruments guidance	
Image-guided	Yes	Identical
Display real-time instrument position on preoperative images	Yes	Identical
Mechanical guidance for surgical instruments	Yes	Identical
Instrument guide position adjustment	Automatic (robotized)	Identical
Surgeon carries out final gesture through the instrument guide with traditional surgical instrument	Yes	Identical
Instrument fixation	Instruments are mounted onto robot arm's flange	Identical
Instrument calibration method	Factory calibration	Identical
Components	• Navigation probe • Standard tool holder • Endoscope holder • Microdrive holder • Optical sensor • Fiducial markers • Head holder adaptor • Leksell frame registration plates	• Navigation probe • Standard tool holder • Endoscope holder • Microdrive holder • Optical sensor • Fiducial markers • Head holder adaptor • Leksell frame registration plates • CRW Frame Justification: Addition of a compatibility to a new head holder ("CRW Frame") by adding a mechanical component the "CRW Frame Adaptor" to immobilize the patient's head specifically during DBS surgery procedure
Patient immobilization	Yes - The device is attached to the head holder or the frame via an	Yes – The device is attached to a head holder or a frame via an adaptor

Device	ROSA BRAIN 3.0.0.0 (K151359)	ROSA BRAIN 3.0.0.5 (submission subject)
	adaptor	Different - Same principle with addition of a new head holder CRW Frame
Device mobility	Yes - Mobile stand with wheels, immobilized with 4 stabilization feet	Identical
Vigilance system	Yes - pedal	Identical

VII PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for ROSA BRAIN device has been conducted in accordance with FDA Guidance Document: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* The evaluation reveals that biocompatibility requirements are met by the ROSA BRAIN device.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on ROSA BRAIN. The device complies with recognized electrical safety standards: IEC 60601-1 standard for electrical safety and IEC 60601-1-2 standard for electromagnetic compatibility. The EMC testing was performed according to the FDA EMC guidance document "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices" issued in July 11, 2016.

Software Verification and Validation Testing

Software tests were conducted to satisfy the requirements of the FDA Guidance for the *Content of Premarket Submissions for Software Contained in Medical Devices and IEC 62304 Standard (Medical Device Software – Life Cycle Process)*. The software was considered as a "major" level of concern, since a failure of the software could result in serious injury or death to the patient.

Software verification activities were performed during the "Design, coding & testing" and "Verification" phases of software lifecycle. Outputs generated during these phases include:

- Code walkthroughs
- Unit test reports
- Integration test reports
- System test reports
- Overall software test report
- Verification test reports
- Overall software verification report

Code inspections and software tests at the unit, integration and system levels were performed according to the Software Test Plan. Verification tests were performed for each software requirement according to the Software Verification Plan.

Conformity of software with the user needs and intended use of the device were performed through the "Validation" phase of the ROSA Brain device.

Cleaning- and Sterilization Validation

MEDTECH has performed an automated cleaning validation according to FDA Guidance Document *Reprocessing of Reusable Medical Devices: Information for Manufacturers* and AAMI TIR 30 Technical report. Additionally, the sterilization validation was performed according to ISO 17665-1, ISO 17664, ANSI/AAMI ST79, and AAMI TIR 12 Technical report using two cycles.

Animal studies

Data from animal studies were not required to support the safety and effectiveness of ROSA Brain.

Clinical Studies

Clinical data were not required to support the safety and effectiveness of ROSA Brain. All validation was performed based on non-clinical performance tests.

VI SUMMARY OF NON CLINICAL PERFORMANCE TESTING

Test	Test Method Summary	Results
System applicative accuracy In vitro testing	Performance bench Testing in compliance with internal medtech /Zimmer Biomet robotics procedures	Testing on the subject device was performed and demonstrated to be substantially equivalent to the predicate device: • Robot arm positioning accuracy< 0.75 mm RMS • Device applicative accuracy< 2mm
Electrical safety and electromagnetic compatibility (EMC)	Testing in compliance with the IEC 60601-1:2005/A1:2012 and IEC 60601-1-2:2014	Evaluation and testing were performed on the subject device and demonstrated to be substantially equivalent to the predicate device.
Biocompatibility testing	Testing in compliance with FDA Guidance "Use of International Standard IS10993, Biological evaluation of medical Devices Part 1".	The following non clinical tests were performed on the predicate device : Cytotoxicity, Sensitization , Irritation and Acute systemic toxicity The subject devices were evaluated against the predicate testing and determined to be substantially equivalent.
Software Verification and Validation Testing	Software verification testing in compliance with FDA guidance "General Principles of Software Validation" and IEC 62304: 2006	Evaluation and testing were performed on the subject device and demonstrated substantially equivalent performance to identified predicate device
Cleaning- and Sterilization Validation	Testing in compliance with FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" and the following standards: ISO 17665-1 Sterilization of health care	Evaluation was performed of the subject device and demonstrated to be substantially equivalent to the identified predicate devices.

	products -Moist heat - Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices and ISO 17664-Sterilization of medical devices - -Information to be provided by the manufacturer for the processing of re-sterilizable medical devices	
Animal studies	Not applicable	Not applicable
Clinical Studies	Not applicable	Not applicable

VII CONCLUSIONS

ROSA BRAIN (v3.0.0.5) is substantially equivalent in design and intended use to the predicate device – ROSA BRAIN (3.0.0.0) (K151359). Any differences between the subject and predicate device have no significant influence on safety or effectiveness as established through performance testing. Therefore, ROSA BRAIN (v3.0.0.5) raises no new issues of safety or effectiveness when compared to the predicate device.