February 7, 2019

Medtech S.A.
Serge Tabet
RA Manager
ZAC Eureka - 900 Rue du Mas de Verchant
Montpellier, 34000 Fr

Re: K182417
Trade/Device Name: ROSA ONE Brain Application
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 19, 2018
Received: November 23, 2018

Dear Serge Tabet:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Matthew C. Krueger -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)*
K182417

Device Name
ROSA ONE Brain Application

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 neurosurgery 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

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Dated prepared: November 19, 2018

II DEVICE

Name of Device:	**ROSA ONE Brain application**
Common Name:	Computer-assisted surgical device
Classification Name:	Stereotaxic Instrument (21 CFR 882.4560)
Classification Panel:	Neurology
Regulatory Class:	II
Product Code:	HAW (Brain)
510k #:	K182417

III PREDICATE DEVICES

ROSA BRAIN, manufactured by Medtech S.A., K172444, cleared on March 28, 2018

IV DEVICE DESCRIPTION

The ROSA One Brain application device is a robotized image-guided device that assists the surgeon during brain surgeries.

It provides guidance of any surgical instruments compatible with the diameter of the adaptors supplied by Medtech. It allows the user to plan the position of instruments or implants on medical images and provides stable, accurate and reproducible guidance in accordance with the planning.

The device is composed of a robot stand with a compact robotic arm and a touch screen.

Different types of instruments may be attached to the end of the robot arm and changed according to the intended surgical procedure. For Brain applications, these neurosurgical instruments (e.g. biopsy needle, stimulation or recording electrode, endoscope) remain applicable for a variety of procedures as shown below in **Figure 5.1** for the placement of recording electrodes.

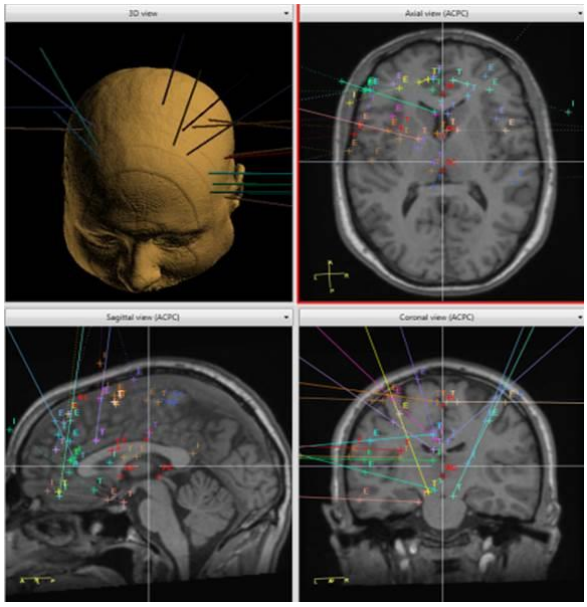

Figure 5.1: Example planning for recording electrodes in a stereo electroencephalography (SEEG) procedure with the ROSA ONE Brain application

The touchscreen ensures the communication between the device and its user by indicating the actions to be performed with respect to the procedure.

Adequate guidance of instruments is obtained from three-dimensional calculations performed from desired surgical planning parameters and registration of spatial position of the patient.

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 neurosurgery may be appropriate.

VI COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device	ROSA BRAIN (K172444)	ROSA ONE 3.1 Brain application *(submission subject)*	Comparison Analysis
Device description and indications for use			
General device description	Computer controlled electromechanical 6-axis multi-jointed arm	Computer controlled electromechanical arm providing guidance of neurosurgical instruments	Identical
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.	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 neurosurgery may be appropriate.	Identical
Where used	Neurosurgical operating room	Neurosurgical operating room	Identical
User	Neurosurgeon	Neurosurgeon	Identical
Anatomical site	Head	Head	Identical
Principle of operation	• Preoperative images • Surgical planning • Patient registration • Guidance of instruments	• Pre & intraoperative images • Surgical planning • Patient registration • Guidance of instruments	Identical
Preoperative images & surgical planning			
Images type	3D MRI / CT	3D MRI / CT	Identical
DICOM compliance	Yes	Yes	Identical
Merge images (multimodality image fusion capability)	Yes	Yes	Identical

Device	ROSA BRAIN (K172444)	ROSA ONE 3.1 Brain application *(submission subject)*	Comparison Analysis
Integrated planning software	ROSANNA BRAIN (Medtech)	ROSANNA BRAIN (Medtech)	Identical
Define regions of interest (ROI)	Yes	Yes	Identical
Trajectory planning parameters	Entry point, target point, length of the instrument, diameter, name, color	Entry point, target point, length of the instrument, 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)	Parameters for planning trajectories: entry point, target point, length of the instrument, diameter, name, security radius (10mm by default), security aperture (10° by default)	Identical
Save/load planning	Yes	Yes	Identical
Patient Registration			
Localization means	Robot arm absolute encoders	Robot arm absolute encoders	Identical
Controller	Axis controller for each joint Kinematic transformation between the Cartesian space and joint space Supervisor module	Axis controller for each joint Kinematic transformation between the Cartesian space and joint space Supervisor module	Identical
Patient registration methods	• Fiducial markers • Optical registration device • Stereotactic frame (fiducials mounted on the frame)	• Fiducial markers (skin, bone) • Optical registration device Stereotactic frame (fiducials mounted on the frame)	Identical
Fiducial markers registration with pointer probe	Yes	Yes	Identical
Surface matching registration with optical distance sensor	Yes	Yes	Identical
Laser class for optical registration	Class 2 laser Wavelength – 658 nm, Maximum output – 1 mW (complies with 21 CFR 1040.10)	Class 2 laser Wavelength – 658, Maximum output – 1 mW (complies with 21 CFR 1040.10)	Identical

Device	ROSA BRAIN (K172444)	ROSA ONE 3.1 Brain application *(submission subject)*	Comparison Analysis
Cooperative movement	Yes	Yes	Identical
Accuracy verification on anatomical landmarks	Yes	Yes	Identical
Instruments guidance			
Image-guided	Yes	Yes	Identical
Real time display of the instrument position	Yes	Yes	Identical
Provide guidance for surgical instruments	Yes	Yes	Identical
Instrument guide position adjustment	Automatic (robotized)	Automatic (robotized)	Identical
Surgeon carries out final gesture through the instrument guide with traditional surgical instrument	Yes – through the instrument guide	Yes – through the instrument guide	Identical
Instrument fixation	Instruments are mounted onto robot arm's flange	Instruments are mounted onto robot arm's flange	Identical
Instruments	Instrument holder, endoscope holder and adaptors, optical sensor	Instrument holder, endoscope holder and adaptors, optical sensor	Identical with addition of two new transnasal endoscopy instrument holders and six new PEEK instrument adaptors
Instrument calibration method	Factory calibration	Factory calibration	Identical
Associated equipment	• 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 • Leksell frame registration plates	Identical

Device	ROSA BRAIN (K172444)	ROSA ONE 3.1 Brain application *(submission subject)*	Comparison Analysis
	• CRW Frame	• CRW Frame	
Patient immobilization	Yes - The device is attached to the head holder or the frame via an adaptor.	Yes - The device is attached to the head holder or the frame via an adaptor	Identical
Device mobility	Yes - Mobile stand with wheels, immobilized with 4 stabilization feet	Yes - Mobile stands with wheels; Robot stand immobilized with stabilization feet	Identical
Vigilance system	Yes – foot pedal	Yes – foot pedal	Identical
Sterility	Non-sterile and sterile instruments Disposable sterile drapes for the robot arm and touch screen	Non-sterile and sterile instruments Disposable sterile drapes for the robot arm and touch screen	Identical

VII PERFORMANCE DATA

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

Biocompatibility testing

The biocompatibility evaluation for the ROSA ONE Brain application 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 ONE device.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on ROSA ONE Brain application. 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 ONE Brain application.

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 ONE Brain application.

Clinical Studies

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

VIII 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 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	Evaluation was performed of the subject device and demonstrated to be substantially equivalent to the identified predicate device.
Animal studies	Not applicable	Not applicable
Clinical Studies	Not applicable	Not applicable

IX CONCLUSIONS

ROSA ONE Brain application is substantially equivalent in design and intended use to the predicate device – ROSA BRAIN (K172444).

Any differences between the subject and the predicate device have no significant influence on safety or effectiveness as established through performance testing. Therefore, ROSA ONE Brain application raises no new issues of safety or effectiveness when compared to the predicate device.