DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 18, 2015

Medtech S.A.
Ms. Colette Maurin
Regulatory Affairs Director
ZAC Eurêka
900 rue du Mas de Verchant
34000 Montpellier, France

Re: K151359
Trade/Device Name: ROSA Brain
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 16, 2015
Received: November 20, 2015

Dear Ms. Colette Maurin:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151359

Device Name
ROSA Brain

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.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: December 17, 2015

II DEVICE

Name of device: ROSA Brain
Common Name: Computer-assisted surgical device
Classification name: Stereotaxic Instrument (21CFR 882.4560)
Regulatory class: II
Code product: HAW

III PREDICATE DEVICE

ROSA Surgical Device, manufactured by Medtech S.A., K101797, cleared September 23, 2010

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.

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 Surgical Device (K101791)**	**ROSA Brain (submission subject)**
Indications for use	Intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide. The system is intended to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). Indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate.	Different Justification: Minor rewording 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
Where used	Neurosurgical operating room	Identical
User	Neurosurgeon	Identical
General device description	Computer controlled electromechanical 6-axis multi-jointed arm	Identical

Device	ROSA Surgical Device (K101791)	ROSA Brain (submission subject)
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 2.0 (Medtech)	Different Justification: Minor changes – Upgraded version ROSANNA BRAIN 3.0 (Medtech)
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
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	Different Justification: • Fiducial markers • Optical registration device • Stereotactic frame (fiducials mounted on the frame)
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, laser beam)	Identical

Device	ROSA Surgical Device (K101791)	ROSA Brain (submission subject)
	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 • Optical sensor • Fiducial markers • Head holder • Stereovision system • 3D visualization headset • Light source	Different Justification: • Navigation probe • Standard tool holder • Endoscope holder • Optical sensor • Fiducial markers • Head holder • Microdrive holder • Leksell frame registration plates The stereovision system, headset and light source are not part of the device. Registration plates were designed for the stereotactic frame registration method.
Patient immobilization	Yes - The device is attached to the head holder or the frame via an adaptor	Different Justification: Same principle with minor redesign of the head holder and frame adaptors
Device mobility	Yes - Mobile stand with wheels, immobilized with 3 stabilization feet	Different Justification: Same principle with 4 stabilization feet instead of 3
Vigilance system	Yes - hand control	Different Justification: 1-pedal footswitch

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 blue book memorandum #G95-1 entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing", May 1, 1995. 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.

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 (see ROSA3-052A)

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 requirements 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.

Mechanical and acoustic testing

The 510(k) does not contain clinical information for the ROSA Brain.

Animal study

The 510(k) does not contain animal study test results for the ROSA Brain.

Clinical Studies

The 510(k) does not contain clinical information for the ROSA Brain.

VI CONCLUSIONS

The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the ROSA Brain Device should perform as intended in the specified use conditions. The non-clinical data demonstrate that the ROSA Brain Device performs comparably to the predicate device that is currently marketed for the same intended use.