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

January 4, 2016

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

Re: K151511
Trade/Device Name: ROSA Spine
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 14, 2015
Received: December 16, 2015

Dear Ms. 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 Parts 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" (21CFR 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,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 - INDICATIONS FOR USE

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)*
K151511

Device Name
ROSA Spine

Indications for Use *(Describe)*
The device is intended for the spatial positioning and orientation of instrument holders or tool guides to be used by surgeons to guide standard neurosurgical instruments during spine surgery. Guidance is based on an intra-operative plan developed with three dimensional imaging software provided that the required fiducial markers and rigid patient anatomy can be identified on 3D CT scans. The device is indicated for the placement of pedicle screws in lumbar vertebrae with a posterior approach

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

FORM FDA 3881 (8/14) Page 1 of 1

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:
Colette Maurin
Regulatory Affairs Director
c.maurin@medtechsurgical.com

Date prepared: December 31, 2015

II DEVICE

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

III PREDICATE DEVICE

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

StealthStation System, manufactured by Medtronic Navigation Inc., K133444, cleared July 25, 2014

IV DEVICE DESCRIPTION

ROSA Spine is a computer controlled electromechanical arm providing guidance of neurosurgical instruments during spinal surgery.

ROSA Spine assists the surgeon in planning the position of instruments relative to intraoperative images.
Adequate position of the instrument holder is obtained from three-dimensional calculations performed from desired surgical planning parameters and registration of spatial position of the patient.
ROSA Spine provides a stable, accurate and reproducible mechanical guidance of neurosurgical instruments in accordance with an intraoperative planning.

V INDICATIONS FOR USE

ROSA Spine is intended for the spatial positioning and orientation of instrument holders or tool guides to be used by surgeons to guide standard neurosurgical instruments during spine surgery.
Guidance is based on an intra-operative plan developed with three dimensional imaging software provided that the required fiducial markers and rigid patient anatomy can be identified on 3D CT scans.
The device is indicated for the placement of pedicle screws in lumbar vertebrae with a posterior approach

VI COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Predicate Devices		Subject Device
Device	**ROSA Surgical Device** *(K101791)*	**StealthStation System** *(K133444)*	**ROSA Spine** *(Submission subject)*
Device description and indications for use			
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.	Intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone or a vertebra, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.	ROSA Spine is intended for the spatial positioning and orientation of instrument holders or tool guides to be used by surgeons to guide standard neurosurgical instruments during spine surgery. Guidance is based on an intra-operative plan developed with three dimensional imaging software provided that the required fiducial markers and rigid patient anatomy can be identified on 3D CT scans. The device is indicated for the placement of pedicle screws in lumbar vertebrae with a posterior approach
Where used	Operating room	Operating room	Operating room
User	Neurosurgeon	Neurosurgeon Orthopedic surgeon	Neurosurgeon Orthopedic surgeon
General device description	Computer controlled electromechanical arm providing guidance of neurosurgical instruments	Navigation system helping the surgeon in manual guidance of navigated neurosurgical instruments	Computer controlled electromechanical arm providing guidance of neurosurgical instruments
Anatomical site	Head	Head, spine	Spine
Surgical approach	Open, minimally invasive or percutaneous	Open, minimally invasive or percutaneous	Open, minimally invasive or percutaneous
Technology			
Principle of operation	- Preoperative images; - Surgical planning; - Patient registration; - Guidance of instruments	For Spine application: - Intraoperative images; - Patient registration; - Surgical planning; - Real-time tracking of navigated instruments	- Intraoperative images; - Patient registration; - Surgical planning; - Guidance of instruments; - Real-time tracking of navigated instruments
Input images	3D pre-operative exam	3D pre-operative exam 3D intra-operative exam 2D intra-operative exam	3D intra-operative exam
DICOM compliance	Yes	Yes	Yes
Integrated planning Software	ROSANNA (Medtech)	Synergy Spine software (Medtronic)	ROSANNA SPINE (Medtech)
Save/load planning	Yes	Yes	Yes
Merge images functionality	Yes	Yes	Yes

	Predicate Devices		Subject Device
Device	**ROSA Surgical Device** *(K101791)*	**StealthStation System** *(K133444)*	**ROSA Spine** *(Submission subject)*
Trajectory planning parameters	Entry point, target point, length of the instrument, diameter	Entry point, target point, length of the instrument, diameter	Entry point, target point, length of the instrument, diameter
Localization means	Robot arm absolute encoders	Optical system (infrared camera) or electromagnetic system	Robot arm absolute encoders + optical system (infrared camera)
Image-guided	Yes	Yes	Yes
Controller	Axis controller for each joint Kinematic transformation between the Cartesian space and joint space Supervisor module	No controller – The instrument is manually positioned by the surgeon	Axis controller for each joint Kinematic transformation between the Cartesian space and joint space Supervisor module
Patient registration method	Fiducial markers (skin) Optical registration device	Point-to-point registration with anatomical markers	3D registration with X-Ray pattern containing radio-opaque markers
Accuracy verification on anatomical landmarks	Yes (probe, laser beam)	Yes (probe)	Yes (probe)
Laser class for optical system	Class 2 laser Wavelength – 650 nm, Maximum output – 1 mW (complies with 21 CFR 1040.10)	Class 2 laser Wavelength – 635 nm, Maximum output – 1 mW (complies with 21 CFR 1040.10)	Class 2 laser Wavelength – 635 nm, Maximum output – 1 mW (complies with 21 CFR 1040.10)
Real time display of the instrument position	Yes	Yes	Yes
Provide guidance for instruments	Yes – Instruments are mounted onto the robot arm. The guidance is robotized.	No - The instrument is manually positioned by the surgeon.	Yes – Instruments are mounted onto the robot arm. The guidance is robotized.
Surgeon carries out the final gesture	Yes – through the instrument guide	Yes – the surgeon holds the instrument	Yes – through the instrument guide
Instrument	Instrument holder, endoscope holder and adaptors, optical sensor	Navigated instruments	Instrument holder, cannula, adaptors, navigated instruments
Instrument calibration method	Factory calibration	Factory calibration	Factory calibration
Associated equipment	• 3D imaging system • Fiducial markers • Head holder • Endoscope • Stereovision system • 3D visualization headset • Light source	• 3D/2D imaging system • Retro-reflective sterile spheres • Implants and instrumentation	• 3D imaging system • Retro-reflective sterile spheres • Implants and instrumentation
Patient immobilization	Yes - The device is attached to the head holder via an adaptor.	No – a reference is fixed in the patient's iliac crest or clamped on the patient's spinous for tracking system	No – a reference is fixed in the patient's iliac crest for tracking system
Device mobility	Yes - mobile stand with wheels, immobilized with stabilization feet	Yes - mobile stands with wheels; Stands immobilized with wheels brakes	Yes - mobile stands with wheels; Robot stand immobilized with stabilization

	Predicate Devices		Subject Device
Device	**ROSA Surgical Device** *(K101791)*	**StealthStation System** *(K133444)*	**ROSA Spine** *(Submission subject)*
			feet and camera stand immobilized with wheels brakes
Sterility	Non-sterile and sterile instruments Disposable sterile drapes on device	Non-sterile and sterile instruments Disposable sterile drapes on device	Non-sterile and sterile instruments Disposable sterile drapes on device
Power supply	110 V	115 V	115 V
Footprint	Robot stand ≈ 91cm × 66cm	Surgeon cart ≈ 60cm x 63cm Staff cart ≈ 58cm x 61cm	Robot stand ≈ 121cm × 65cm Camera stand ≈ 81cm x 76cm
Performance			
- Robot absolute accuracy **- Robot repeatability**	< 0.75 mm < 0.10 mm	Not applicable	< 0.75 mm < 0.10 mm
Guidance application accuracy	< 2.00 mm	Not applicable	< 2.00 mm
Navigation accuracy	Not applicable	< 2.00 mm	< 1.50 mm

VII PERFORMANCE DATA

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

Biocompatibility testing

The biocompatibility evaluation for ROSA Spine device has been conducted in accordance with ISO 10993 standards and 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 Spine device.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on ROSA Spine. The device complies with recognized electrical safety standards: IEC 60601-1 standard for electrical safety and IEC 60601-1-2 standard for electromagnetic compatibility.

Device performance Testing

Device performance tests were performed to validate the absolute accuracy and repeatability of the robot arm, the application accuracy of the device, and the navigation accuracy according to ASTM F2554-10

Testing were conducted on cadaveric specimens in a simulated clinical environment to evaluate the device safety and effectiveness (clinical performance).

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 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 Spine device.

Animal study

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

Clinical Studies

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

VIII CONCLUSIONS

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