



5 - 510(K) SUMMARY

[As Required by 21 CFR 807.92]
Summary of Safety and Effectiveness

K101791
SEP 23 2010

- 1 Submitter** MedTech S.A
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- Preparation date June 10, 2010
Revision date July 20, 2010
Revision date August 18, 2010
Revision date September 02, 2010
- 2 Device name**
- Trade Name ROSA Surgical Device
Common Name Computer-assisted surgical device
Code product and classification name Stereotaxic Instrument (HAW), 21 CFR Section 882.4560
- 3 Predicate devices**
- ROSA Surgical Device, manufactured by MedTech SAS, K092239, cleared November 17, 2009
- StealthStation Treatment Guidance Platform, manufactured by Medtronic Surgical Navigation Technologies, K001801, cleared June 30, 2000
- VectorVision Cranial / ENT, manufactured by BrainLAB AG, K023651, cleared February 17, 2004
- Frameless Neuromate Stereotactic System, manufactured by Integrated Surgical Systems, Inc., K991081, cleared June 25, 1999
- 4 Description**
- ROSA Surgical Device is a computer controlled electromechanical arm. It is intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide.
- Guidance is based on a pre-operative plan developed with three-dimensional imaging software, and uses fiducial markers or optical registration.
- The system is intended for use by neurosurgeons to guide standard neurosurgical instruments.



Explanation of how the device operates

ROSA Surgical Device assists the neurosurgeon in planning the position of instruments relative to preoperative images.

Adequate position of the instrument holder is obtained from three-dimensional calculations performed from desired surgical planning parameters and registration of spatial positions of patient head with fiducial markers or a laser telemeter.

When using the fiducial markers registration, ROSA Surgical Device can be shifted into a "cooperative mode" during which the surgeon can manually move the arm anywhere in the operating field by simply grabbing the tip. Pinpoint collection of fiducial markers is carried out with ROSA and its navigation probe with the cooperative mode.

When using the optical registration, ROSA Surgical Device can be shifted into a "cooperative mode" during which the surgeon can manually move the arm with the laser telemeter at its end and digitize selected anatomical landmarks on the patient's head. Then, the robot arm automatically scans an appropriate surface of the patient's head.

ROSA Surgical Device provides a stable, accurate and reproducible mechanical guidance of neurosurgical instruments in accordance with a preoperative planning.

5 Intended use

ROSA Surgical Device is a computer-controlled electromechanical arm. It is intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide.

Guidance is based on a pre-operative plan developed with three-dimensional imaging software, and uses fiducial markers or optical registration. The system is intended for use by neurosurgeons to guide standard neurosurgical instruments.

It is indicated for any neurosurgical condition in which the use of stereotactic surgery may be appropriate.



6 Performance data

Testing was carried out to assure compliance with recognized electrical safety standards: IEC 60601-1 standard for electrical safety and IEC 60601-1-2 standard for electromagnetic compatibility.

Tests were also carried out to satisfy the requirements of the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and IEC 62304 (Medical Device Software – Life Cycle Process).

Device performance tests were performed to validate the absolute accuracy and repeatability of the device (robot arm).

Device performance tests were performed to validate the application accuracy of the device for fiducial markers and optical registration.

Testing protocol

The test bench permits to simulate a neurosurgical procedure. Test consists in thoroughly following the ROSA stereotactic procedure and measuring the distance between the targeted point and the attained instrument tip position. Equipment for this test includes a phantom skull featuring small metallic balls that materialize target points and a portable CMM for the measures (FARO Titanium arm, 50 μ m single point accuracy). Application accuracy is computed as the mean distance error for the N targets.

Expected results for ROSA surgical device for an in vitro application should yield a mean accuracy equivalent to other commonly used surgical localization systems: below 2 mm.

Tests results

For fiducial markers: The mean target localization accuracy was evaluated in vitro on a total of 45 measurements collected by approaching nine targets distributed within a volume comparable to a human head. Average in vitro application accuracy is below than 2 mm.

For optical registration: The mean target localization accuracy was evaluated in vitro on a total of 45 measurements collected by approaching various targets distributed within a volume comparable to a human head. Average in vitro application accuracy is below than 2 mm.

ROSA application accuracy with optical registration is equivalent to the application accuracy of the previous cleared ROSA (below than 2 mm).



7 Substantial equivalence summary The technological characteristics, features, specifications, materials, mode of operation, and intended use of the ROSA Surgical Device are substantially equivalent to the predicate devices cited above.

The differences that exist between the devices do not raise new issues of safety or effectiveness regarding the ROSA Surgical Device.

COMPARISON TABLE

Reference	Frameless Neuromate Stereotactic System K991081	VectorVision Cranial / ENT K023651	ROSA Surgical Device K092239	StealthStation Treatment Guidance Platform K001801	ROSA Surgical Device (for new submission)
Design					
General device description	Computer controlled electromechanical multi-jointed arm indicated for use as a stereotactic instrument	Neuronavigation system providing localization means for neurosurgical instruments	Computer controlled electromechanical multi-jointed arm indicated for use as a stereotactic instrument	Neuronavigation system providing localization means for neurosurgical instruments	Computer controlled electromechanical multi-jointed arm indicated for use as a stereotactic instrument
Localization means	Robot arm absolute encoders	Infrared cameras	Robot arm absolute encoders	Infrared cameras (NDI Polaris system)	Robot arm absolute encoders
Image-guided	Yes	Yes	Yes	Yes	Yes
Integrated planning software	No (third-party software)	Yes	Yes	Yes	Yes
Registration method	Bone-mounted ultrasound device	Fiducial markers "Softouch" mechanical probe system Laser scanning device (Z-touch system)	Fiducial markers	Fiducial markers "Tracer" mechanical probe system Laser registration device (Fazer)	Fiducial markers Optical registration device
Instrumentation	Laser pointer Tool holder	Probes Frameless biopsy system	Navigation probe Tool holder	Probes Frameless biopsy system	Navigation probe Tool holder Laser pointer
Instrument fixation	Instruments are mounted onto robot arm's flange.	Freehand instruments. A localizer is attached to each navigated instrument.	Instruments are mounted onto robot arm's flange.	Freehand instruments. A localizer is attached to each navigated instrument.	Instruments are mounted onto robot arm's flange.
Instrument calibration method	Factory calibration	Intra operative	Factory calibration	Intra operative	Factory calibration
System immobilization between the patient and the device	Yes	Not necessarily A localizer is attached to the head holder as a reference	Yes	Not necessarily A localizer is attached to the head holder as a reference	Yes
Patient immobilization (head holder)	Yes	Yes	Yes	Yes	Yes
Planning & Navigation Software					
Path planning and control Software	VoXim™ (IVS Solutions AG)	VectorVision Flex (BrainLAB)	ROSANNA (MedTech)	StealthStation (Medtronic)	ROSANNA (MedTech)
CT & MRI modalities	Yes	Yes	Yes	Yes	Yes
Merge images	Yes	Yes	No	yes	Yes
Save/load path planning	Yes	Yes	Yes	yes	Yes
System operation					



**PREMARKET NOTIFICATION 510(K) SUBMISSION
ROSA SURGICAL DEVICE**

Reference	Frameless Neuroamate Stereotactic System K991081	VectorVision Cranial / ENT K023651	ROSA Surgical Device K092239	StealthStation Treatment Guidance Platform K001801	ROSA Surgical Device (for new submission)
Fiducial markers registration with pointer probe	No	Yes	Yes	Yes	Yes
Optical registration with laser telemeter	No	Yes	No	Yes	Yes
Registration based on ultrasound measures	Yes	no	No	No	No
Cooperative movement	No	No	Yes	No	Yes
Accuracy verification on anatomical landmarks	Yes (laser pointer)	Yes (pointer probe)	Yes (navigation probe)	Yes (pointer probe)	Yes (navigation probe, laser beam)
Display real-time instrument position on preoperative images	Yes	Yes	Yes	Yes	Yes
Provide mechanical guidance for surgical instruments	Yes	No	Yes	Only with the frameless biopsy	Yes
Instrument guide position adjustment	Automatic (robotized)	Manual	Automatic (robotized)	Manual	Automatic (robotized)
Surgeon carries out final gesture through the instrument guide	Yes	Yes	Yes	Yes	Yes
Indication(s) for use					
Indication for use	Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope).	Intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure can be identified to a CT or MR based model.	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). 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. Indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure can be identified to a CT or MR based model.	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.
Anatomical site	Head	Head, ENT	Head	Head, Spine, ENT	Head
User	Neurosurgeon	Neurosurgeon	Neurosurgeon	Neurosurgeon	Neurosurgeon
Associated equipments	Sterile drapes	Sterile drapes Fiducial markers Neurosurgical head holder	Sterile drapes Fiducial markers Neurosurgical head holder Light source (for visualization)	Sterile drapes Fiducial markers Neurosurgical head holder Surgical microscope	Sterile drapes Fiducial markers Neurosurgical head holder Light source (for visualization)



SIMILARITIES AND DIFFERENCES

SIMILARITIES

All five devices are intraoperative stereotactic instruments used by neurosurgeons for assisting in the spatial positioning and orientation of a neurosurgical instrument.

ROSA Surgical device is substantially equivalent to:

- the Neuromate, StealthStation and VectorVision devices for assisting the spatial positioning and orientation of an endoscope (neurosurgical instrument).
- the cleared ROSA, Neuromate, StealthStation and VectorVision devices concerning the preoperative planning process. All five take as input data CT or MRI DICOM 3.0 medical images. The neurosurgeon performs its preoperative plan by defining entry and target points on 3D and 2D views. Preoperative plan can be performed the day before surgery.
- the cleared ROSA, StealthStation and VectorVision devices concerning the manual registration processes. It uses the same Image Guided Surgery multi-modality fiducial markers and is based on the same mathematical computations (3D rigid transformation). The application accuracy is substantially equivalent.
- the StealthStation and VectorVision devices with regard to the optical registration processes. It uses the same Image Guided Surgery multi-modality and is based on the same mathematical computations (3D rigid transformation). The application accuracy is substantially equivalent.
- the StealthStation which uses a laser telemeter for the optical registration.
- the Neuromate device which provides a laser system for the navigation and accuracy verification.
- the cleared ROSA and Neuromate devices as it provides mechanical guidance for neurosurgical instruments and allows optimal access according to patient anatomy. Both are computer controlled electromechanical multi-jointed arms with factory calibrated instruments.
- the cleared ROSA Surgical Device as it provides cooperative movement where the surgeon can manually move the arm anywhere in the operating field simply by directing the surgical instrument attached to the robot arm.

ROSA Surgical Device combines the planning and registration functionalities of the Neuromate, StealthStation and VectorVision systems and the mechanical guidance functionality of the cleared ROSA system and Neuromate.

DIFFERENCES

StealthStation and VectorVision devices use a Polaris system (infrared cameras) for locating the position of the neurosurgical and registration instruments held by the surgeon, a localizer is attached to the instrument. ROSA and Neuromate devices provide mechanical guidance for neurosurgical and registration instruments, both are computer controlled electromechanical multi-jointed arms with embedded sensors to locate the position of instruments.

StealthStation device uses a Polaris system for locating the position of laser telemeter held by the surgeon during optical registration. While the VectorVision device uses a Polaris system for locating the position of the laser spot on the patient face.

Neuromate device uses a registration method based on ultrasound measures. Rosa, StealthStation and VectorVision devices provide an optical registration method based on laser measures.

ROSA and Neuromate devices use a mechanical immobilization system between the head holder attached to the patient and the device. StealthStation and VectorVision devices provide a localizer attached to the patient head.



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

Medtech SAS
c/o Ms. Cécile Genevieve
Quality Regulation Affairs Manager
Parc Euromedecine, Bâtiment 8
1006, rue de la croix verte
34090 Montpellier
France

SEP 23 2010

Re: K101791

Trade/Device Name: Rosa Surgical Device
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: August 19, 2010
Received: August 23, 2010

Dear Mr. Nahum:

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.

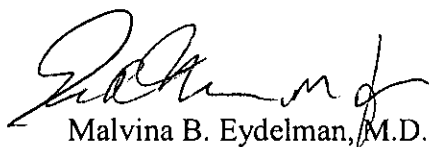
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



4 - INDICATIONS FOR USE

510(k) Number (if known): K101791

K101791

Device Name: ROSA Surgical Device

SEP 23 2010

Indications for Use: ROSA Surgical Device is a computer-controlled electromechanical arm. It is intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide.

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K101791