K092239

5 - 510(K) SUMMARY

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

1	**Submitter**	MedTech S.A Parc Euromédecine Bâtiment 8 1006 rue de la Croix Verte 34090 Montpellier France
	Contact Person	Bertin NAHUM, President Phone number : (+33) 467 107 740 Fax number : (+33) 467 597 418
	Preparation date Revision date	July 21, 2009 October 12, 2009 November 02, 2009
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**	Frameless Neuromate Stereotactic System, manufactured by Integrated Surgical Systems, Inc., K991081, cleared June 25, 1999 StealthStation Treatment Guidance Platform, manufactured by Medtronic Surgical Navigation Technologies, K001801, cleared June 30, 2000 BRIGIT Surgical Device, manufactured by Zimmer, Inc., K060556, cleared July 31, 2006
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 registration. The system is intended for use by neurosurgeons to guide standard neurosurgical instruments.

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	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 spatial positions of fiducial markers. 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. 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 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 accuracy and repeatability of the device.
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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MedTech S.A.
c/o Mr. Bertin Nahum
10006 Rue de la Croix Verte
Parc Euromedecine batiment 8
34090 Montpellier
France

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Re: K092239
Trade/Device Name: ROSA Surgical Device, Model ROSA 1.1
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: October 12, 2009
Received: October 19, 2009

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.

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" (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 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): K092239

Device Name: ROSA Surgical Device

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.

Guidance is based on a pre-operative plan developed with three-dimensional imaging software, and uses fiducial markers 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.

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

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