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

October 30, 2015

IMRIS Inc.
Mr. Sanjay Shah
Manager, Regulatory Affairs
5101 Shady Oak Road
Minnetonka, Minnesota 55343

Re: K143420
Trade/Device Name: SYMBIS Surgical System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: October 15, 2015
Received: October 26, 2015

Dear Mr. Sanjay Shah:

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)*
K143420

Device Name
SYMBIS Surgical System

Indications for Use *(Describe)*
The SYMBIS Surgical System is a computer-controlled electromechanical arm. The manipulation of the arm is performed by the neurosurgeon. It is intended to be used in the operating room for the spatial positioning and orientation of a biopsy instrument guide.

Guidance is based on a pre-operative plan developed using the Medtronic StealthStation® along with fiducial marker or optical registration. The system is intended for use by neurosurgeons to guide a biopsy needle.

It is intended for use by trained physicians for needle based biopsy.

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."

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part §807.92.

I. SUBMITTER:

Submitter	IMRIS
	5101 Shady Oak Rd
	Minnetonka, MN 55343
	USA
	Establishment Registration Number: 3010326005
Contact Person:	Sanjay Shah, P.Eng.
	Senior Manager, Regulatory Affairs, QA
Telephone:	763.203.6380
Fax:	1 866 992 3224
Email:	sshah@imris.com
Alternate Contact Person:	Daniel Biank, JD, MEng, PE, RAC
	Sr. Vice President, CS, QA, RA and IT
Telephone:	763.203.6310
Fax:	1 866 992 3224
Email:	dbiank@imris.com
Date Prepared:	October 29, 2015

II. DEVICE

Name of the Device:	SYMBIS Surgical System
Common Name:	Neurological Stereotaxic Instrument
Classification Name:	Stereotaxic Instrument (21 CFR 882.4560)
Regulatory Class:	II
Product Code:	HAW

III. PREDICATE DEVICE:

510(k)	Decision Date	Device Name	Manufacturer
K101791	Sep 23, 2010	ROSA Surgical device	MEDTECH SAS 1006 Rue De La Croix Verte Parc Euromedecine (Bat8) Montpellier, FR 34090.

IV. DEVICE DESCRIPTION:

The SYMBIS Surgical System 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 guide. The system is intended for use by trained physicians for needle based biopsy.

The SYMBIS Surgical System consists of the a Surgeon Console, Surgical Cart, Manipulator, Robot Control Cabinet (RCC), Vision System, Platform Room Integration Kit and System Software.

The Manipulator is a master/slave robot configured with either a left arm or a right arm. This arm is mounted to the Surgical Cart. The Surgical Cart is used to transport the Manipulator to and from the operating room, as well as serve as a stationary platform for robotic surgery. The Surgical Cart has an onboard immobilization system to prevent horizontal movement when positioned for surgery. The Instrument Guide is attached to the draped Manipulator and is used by the surgeon to guide the trajectory of a stereotactic instrument (e.g. Biopsy Needle). The Manipulator has six (6) degrees of freedom (DOF). The SYMBIS System provides tremor filtering and motion scaling while the surgeon positions the Manipulator and Instrument Guide to the target position. A Vision System mounted to the Surgical Cart provides the surgeon with a high definition, three-dimensional view of the patient, surgical site, and Manipulator.

The Surgeon Console provides the surgeon with workstation console from which the surgeon controls the Manipulator. The Surgeon Console is located in the operating room. The surgeon, seated at the Surgeon Console, controls all movements of the Manipulator with a hand controller and foot pedal. The upper and middle displays on the Surgeon Console are medical grade, high definition monitors, and the middle monitor is capable of displaying 3 dimensional (3D) images The upper display provides the video output from a third-party navigation system (i.e. Medtronic Stealth station s7/i7). The middle display provides the 3D video output from the field camera, to provide situational awareness to the surgeon when moving the robot near the patient, surgical site, and OR staff. The video from the Vision System, along with the video from the third-party navigation system, is used by the surgeon to manipulate the Instrument Guide to the entry position.

The Robot Control Cabinet (RCC) is an electronics rack and contains the electronics to operate the Surgical Cart, Manipulator and Surgeon Console. It is situated in the hospital's equipment room, adjacent to the surgical suite. The RCC includes the supporting electronic, power supply, and computers for the system.

The platform room integration kit includes motor drivers to run the Manipulator, an OR Pendant with an E-Stop, cable interface mounting plates and system integration cables.

V. INDICATIONS FOR USE:

The SYMBIS Surgical System is a computer-controlled electromechanical arm. The manipulation of the arm is performed by the neurosurgeon. It is intended to be used in the operating room for the spatial positioning and orientation of a biopsy instrument guide.

Guidance is based on a pre-operative plan developed using the Medtronic StealthStation® along with fiducial marker or optical registration. The system is intended for use by neurosurgeons to guide a biopsy needle.

It is intended for use by trained physicians for needle based biopsy.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The SYMBIS Surgical System 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 guide. It is intended for use by trained physicians for needle based biopsy.

The SYMBIS Surgical System uses the Medtronic StealthStation® System, cleared under 510(k) K133444, as the third-party navigation system and the Medtronic Biopsy instrument Kit cleared under K971247 as the third-party instrument. IMRIS is not making any changes to the Medtronic StealthStation® System or the Medtronic Biopsy instrument Kit. The Medtronic Stealth Station (K133444) and Medtronic Biopsy Needle Kit (K971247) are not marketed with the subject device.

The StealthStation® System includes hardware and software that enables real-time surgical navigation using radiological patient images. The navigation system creates a translation map between points of patient anatomy and the corresponding points on radiologic images of the patient. Once this map is established through a process called registration, the software can display the relative position of a tracked instrument to a representation of the patient's anatomy. In this way the images can help guide the surgeon's planning and approach. Prior to operating, the surgeon may create, store, and simulate progression along one or more surgical trajectories. As an aid to visualization, the surgeon may also create and manipulate one or more 2D or 3D models of the anatomy. During surgery, the system tracks the position of specialized surgical instruments in or on the patient anatomy and continuously updates the instrument position on images either by optical tracking or electromagnetic tracking.

The IMRIS SYMBIS Surgical System is comparable to the ROSA Surgical device manufactured by Medtech SAS and cleared under K101791.

510(k)	Decision Date	Device Name	Manufacturer
K101791	Sep 23, 2010	ROSA Surgical Device	MEDTECH SAS

Summary of the technological characteristics of the device compared to the predicate device:

System Characteristic	MEDTECH ROSA Surgical Device (K101791)	IMRIS SYMBIS Surgical System (submission subject)	Comparison
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 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.	The SYMBIS Surgical System is a computer-controlled electromechanical arm. The manipulation of the arm is performed by the neurosurgeon. It is intended to be used in the operating room for the spatial positioning and orientation of a biopsy instrument guide. Guidance is based on a pre-operative plan developed using the Medtronic StealthStation® along with fiducial marker or optical registration. The system is intended for use by neurosurgeons to guide a biopsy needle. It is intended for use by trained physicians for needle based biopsy.	Identical meaning (Different Trade name/component name, we would like to have more focus on training so we have added word for use by trained physicians)
Where Used	Hospital	Hospital	Identical
Users	Surgeon	Surgeon	Identical
General Device	Computer controlled electromechanical multi-jointed arm indicated for	Computer controlled electromechanical multi-jointed arm indicated for use as a	Identical

System Characteristic	MEDTECH ROSA Surgical Device (K101791)	IMRIS SYMBIS Surgical System (submission subject)	Comparison
Description	use as a stereotactic instrument	stereotactic instrument	
Localization means	Robot arm absolute encoders	Robot arm absolute encoders	Identical
Path Planning and control Software	ROSANNA from Medtech	Path planning using the StealthStation® from Medtronic, and control using the SYMBIS control software	Different Justification ROSA uses the path planning capabilities offered by the ROSANNA navigation system. SYMBIS uses the path planning capabilities offered by the Medtronic StealthStation (K133444) navigation system. The control software for the ROSA robot and for the SYMBIS robot are similar in that both respond to movement commands, and map the movement commands to the corresponding movement of the joints of the arm.
Image-guided	Surgeon positions ROSA to desired biopsy trajectory using path planning software	Surgeon positions SYMBIS to desired biopsy trajectory using path planning software	Identical
Registration Method	Fiducial Markers Optical Registration device	Fiducial Markers Optical Registration device	Identical
Instrumentation	Navigation probe, Tool holder Laser Pointer	Navigation probe, Tool holder	Different Justification:

System Characteristic	MEDTECH ROSA Surgical Device (K101791)	IMRIS SYMBIS Surgical System (submission subject)	Comparison
			SYMBIS uses the registration method provided by the Medtronic StealthStation (K133444), which does not require a laser pointer.
Instrument fixation	Instruments are mounted onto robot arm's end effector	Instruments are mounted onto robot arm's end effector	Identical
Instrument calibration method	Calibrated at the factory	Calibrated at the factory	Identical
System immobilization between the patient and the device	Coupled to patient HFD via rigid, adjustable linkage	Coupled to patient HFD via rigid, adjustable linkage	Identical
Patient Immobilization (head holder)	HFD Employed for Head Fixation	HFD Employed for Head Fixation	Identical
CT & MRI modalities	CT and MRI modalities used for pre-operative planning and navigation through the path planning software	CT and MRI modalities used for pre-operative planning and navigation through the path planning software	Identical
Merge images	No support for Biopsy procedures for merging of multi-modal images in the path planning software	No support for Biopsy procedures for merging of multi-modal images in the path planning software	Identical
Save/load path planning	Path planning can be saved and loaded using the path planning software	Path planning can be saved and loaded using the path planning software	Identical

System Characteristic	MEDTECH ROSA Surgical Device (K101791)	IMRIS SYMBIS Surgical System (submission subject)	Comparison
Fiducial markers registration and pointer probe	Optical registration accomplished with fiducial markers and registration probe using the path planning software	Optical registration accomplished with fiducial markers and registration probe using the path planning software	Identical
Optical registration with laser telemeter	Optical registration via laser telemeter supported on ROSA system	Not Supported	Different Justification: SYMBIS uses the registration method provided by the Medtronic StealthStation (K133444), which does not require a laser pointer.
Registration based on ultrasound measures	Ultrasound based registration with patient is not supported with the path planning software	Ultrasound based registration with patient is not supported with the path planning software	Identical
Cooperative movement	Cooperative movement supported by manually guiding the instrument to the entry point	Cooperative movement supported through teleoperation at the surgeon console. Surgeon uses the hand controller to manually guide the instrument to the entry point	Different Justification: In both cases the user manually guides the position of the instrument.
3D Stereoscopic Camera for Situational Awareness	Not Supported	3D Stereoscopic camera for situational awareness supported by SYMBIS	Different Justification: A 3D Camera is used to visualize the Manipulator and patient surgical site, to aid the surgeon in positioning instruments near the patient head
Support for drilling through robot-	Drilling through the robot-held instrument guide is supported with the ROSA	Not supported	Different Justification:

System Characteristic	MEDTECH ROSA Surgical Device (K101791)	IMRIS SYMBIS Surgical System (submission subject)	Comparison
held instrument guide	system		The SYMBIS system is used after the burr hole is created. Therefore support of drilling through a robot-held instrument guide is not required.
Deadman switch for cooperative movement	Deadman switch employed for robotic arm movement	Deadman switch employed for robotic arm movement	Identical
Accuracy verification on anatomical landmarks	Accuracy verification performed on anatomical landmarks via a navigation probe	Accuracy verification performed on anatomical landmarks via a navigation probe	Identical
Application Accuracy	<2 mm	<2 mm	Identical
Display real-time instrument position on preoperative images	Real-time instrument position displayed on pre-operative images in the path planning software	Real-time instrument position displayed on pre-operative images in the path planning software	Identical
Provide mechanical guidance for surgical instruments	Surgeon manually inserts the biopsy needle through the instrument guide	Surgeon manually inserts the biopsy needle through the instrument guide	Identical
Surgeon carries out final gesture through the instrument guide	Surgeon manually advances biopsy needle through instrument guide	Surgeon manually advances biopsy needle through instrument guide	Identical

System Characteristic	MEDTECH ROSA Surgical Device (K101791)	IMRIS SYMBIS Surgical System (submission subject)	Comparison
Associated equipment	Sterile drapes , Fiducial markers and Neurosurgical head holder.	Sterile drapes, Fiducial markers Neurosurgical head holder, Stealth Station	Different Justification for the Stealth Station: SYMBIS uses the Medtronic StealthStation (K133444) for biopsy navigation.
Electrical, Mechanical, Thermal Safety	Industry recognized standards (IEC series of the standards)	Industry recognized standards (IEC series of the standards)	Identical
EMC/EMI compatibility	Industry recognized standards (IEC series of the standards)	Industry recognized standards (IEC series of the standards)	Identical
Human Factors	Unknown	Industry recognized standards (IEC 62366:2007)	Different Justification: The Human Factors study conducted for the SYMBIS robot concluded that there are no significant Human Factors risks with the use of the SYMBIS robot.
Cleaning, Disinfection, and Sterilization applicability	Manipulator arm draped before use with sterile drape, which is disposed after use. Biopsy instrument guide is reprocessed (sterilized) before use	Manipulator arm draped before use with sterile drape, which is disposed after use. Biopsy instrument guide is sterile and disposed after use	Different Justification: The SYMBIS instrument guide is single use (disposable) to reduce the risk on contamination and/or functional degradation from reprocessing.
Biocompatibility	Industry recognized standards (IEC series of the standards)	Industry recognized standards (ISO series of the standards)	Identical

VII. PERFORMANCE DATA

Design Verification and Validation Test (Bench Testing)

The IMRIS SYMBIS Surgical System passed the following tests and meets product specifications. The main tests include

- Design verification testing of the Surgeon Console, Surgical Cart, and Manipulator
- Software verification for Manipulator control software, Surgical Cart software and Robot Control software
- Testing was carried out to assure compliance with recognized electrical safety standards IEC 60601-1 and EMC/EMI standard IEC 60601-1-2 by an independent National Recognized Test Laboratory (NRTL).
- The biocompatibility of the Biopsy Instrument Guide manufactured by IMRIS has been verified by an independent lab. Successful completion of this test demonstrates that the Biopsy Instrument Guide meets biocompatibility requirements as per ISO 10993 series standards
- The sterilization of the SYMBIS Biopsy Instrument Guide has been validated using AAMI/ISO11137-1:2006 and AAMI/ISO11137-2:2012 standards.
- Software testing was carried out to assure compliance with recognized standards IEC 60601-1-6 and IEC 62304:2006 standard.
- Human Factors Evaluation: A summative validation study was conducted with fifteen neurosurgeons. This study was conducted in a simulated surgical procedure that involved safety critical tasks. Training materials and user manuals were developed in concert with the product hardware and software, and were assessed in the validation study. The goals of human factors validation testing were to validate risk mitigations to ensure use-safety and effectiveness of the system, identify and assess any hazards resulting from implemented mitigations and evaluate ease of use.

Performance test data demonstrates that the SYMBIS Surgical System is comparable to the predicate device and that the design output meets the design input requirements. The testing included dimensional measurements, mechanical and functional verification, electrical safety, software verification, sterilization validation, human factor study and system level validation.

Clinical Validation:

No clinical testing was provided with this submission using the SYMBIS Surgical System.

Standards:

Recognition #	Identifier	Title
5-77	AAMI / ANSI ES60601-1:2005/C1:2009/A2:2010	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
19-1	IEC 60601-1-2:2007	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic compatibility –

Recognition #	Identifier	Title
		Requirements and Tests (Edition 3)
13-8	IEC 62304:2006	Medical device software – Software life cycle processes
N/A	IEC 62366:2007	Medical devices -- Application of usability engineering to medical devices
14-407	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
14-297	ANSI/AAMI/ISO 11137-2:2012	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
14-355	ISO 11607-1:2006	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems
14-356	ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing, and assembly processes
14-229	ASTM F1980(R)2011	Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices
14-288	ASTM F1886/F1886M-09	Standard Test Method For Determining Integrity Of Seals For Flexible Packaging By Visual Inspection
14-283	ASTM F88/F88M-09	Standard Test Method For Seal Strength Of Flexible Barrier Materials
14-378	ASTM F1929-98[2004]	Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the SYMBIS Surgical System should perform as intended in the specified use conditions.

The non-clinical data demonstrate that the SYMBIS Surgical System performs comparably to the predicate device that is currently marketed for the same intended use.