November 16, 2017

MASMEC S.p.A.
% Gregory Mathison
President
Regulatory Strategies, Inc.
3924 Cascade Beach Road
Lutsen, Minnesota 55612

Re: K163643
Trade/Device Name: SIRIO H3
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: October 17, 2017
Received: October 24, 2017

Dear Mr. Gregory Mathison:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K163643

Device Name
SIRIO H3

Indications for Use *(Describe)*

SIRIO H3 is a user controlled, stereotactic accessory intended to assist in planning, navigation and manual advancement of one or more instruments, as well as in verification of instrument position and performance during Computed Tomography (CT) guided procedures.

SIRIO H3 is indicated for use with rigid straight instruments such as needles and probes used in CT guided interventional procedures performed by physicians trained for CT procedures.

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.

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510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Applicant:	MASMEC S.p.A.
Trade Name:	SIRIO H3
Common Name:	CT navigation system
Classification Name:	Computed Tomography X-ray System
21CFR Number:	892.1750
Device Classification:	Class II
Product Code:	JAK - System, X-ray, Tomography, Computed
Predicate Devices:	CAS-One IR from CAScination AG (K152473)
Contact	Domenico Marino Director of Regulatory Affairs
Date:	October 15, 2017

Substantially Equivalent to:

The SIRIO H3 is equivalent in intended use, principal of operation and technological characteristics to the CAS-One IR submitted as K152473 with Product Code JAK under 21CFR892.1750.

Description of the device subject to premarket notification

SIRIO H3 is a user controlled, stereotactic accessory intended to assist in planning, navigation and manual advancement of needles (or similar surgical instruments), as well as in verification of theirs position and performance during Computed Tomography (CT) guided procedures.

SIRIO H3 reconstructs a 3D model of the target anatomy from a data set of previously

acquired CT images by means of a semiautomatic algorithm.

The system components are:

- the patient tool
- the needle tool
- direction tool
- guide for needle
- a visualization /elaboration unit
- an infrared optical sensor mounted either on the ceiling of the CT room or on the visualization /elaboration unit

All the tools in contact both with the skin of the patient and with the surgical instruments are sterile disposable.

Indications for Use

SIRIO H3 is a user controlled, stereotactic accessory intended to assist in planning, navigation and manual advancement of one or more instruments, as well as in verification of instrument position and performance during Computed Tomography (CT) guided procedures.

SIRIO H3 is indicated for use with rigid straight instruments such as needles and probes used in CT guided interventional procedures performed by physicians trained for CT procedures.

Materials

All materials used in the manufacture of the SIRIO H3 Disposable Kit are suitable for this use and have been used in numerous previously cleared products.

Non-Clinical Testing

Product testing was completed and met all of the acceptance criteria. Testing included:

- Electrical safety & EMC compatibility according to IEC 60601-1 and IEC 60601-1-2 were conducted. The system was found to conform.
- Dimensional & Visual inspections of the product was performed
- Mechanical and Performance - An accuracy test that evaluated needle insertion configurations of SIRIO H3 was conducted on a phantom simulation of clinical use and was shown to be accurate. Accuracy is defined as the difference between the position of the sensitized real needle and the tip of the figure-guided needle. The accuracy is $\leq$ 2mm / 100mm.

Clinical Evaluation

A clinical evaluation of the SIRIO H3 System was completed by the Department of Diagnostic Imaging of the University Campus of Bio-Medico of Rome. A total of 40 patients were evaluated for lung biopsy procedures. The results of the study concluded the SIRIO H3 System performed as intended in 3D imaging, patient tool use, needle localization, and tracking system operation.

Performance Data

All necessary verification and validation testing has been performed for the SIRIO H3 to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the SIRIO H3 is determined to be substantially equivalent to existing legally marketed devices.

Comparison of Product Features

Trade name	SIRIO H3	CAS-One IR	SE Discussion
Product code	JAK	JAK	Same product code
510(k) number	K163643	K152473	
21CFR	892.1750	892.1750	Same CFR number
Device Classification	II	II	Same – Class II
Device description	SIRIO H3 is a user controlled, stereotactic accessory intended to assist in planning, navigation and manual advancement of needles (or similar surgical instruments), as well as in verification of theirs position and performance during Computed Tomography (CT) guided procedures. SIRIO H3 reconstructs a 3D model of the target anatomy from a data set of previously acquired CT images by means of a semiautomatic algorithm. The system components are: • the patient tool • the needle tool • direction tool • guide for needle • a visualization /elaboration unit • an infrared optical sensor	The system consists of three main components: - A mobile navigation platform: this platform can be moved in and out of radiology rooms and is positioned next to the patient in front of the CT scanner. The platform includes two touch screens, a camera and a computer. - Aiming device with trackable aiming insert: To aim the needles to their correct locations, the system uses an aiming device. The aiming device is attached to a multi-axis mechanical arm that can align the position of the aiming device around the expected needle entry position. The aiming device is first aligned to the desired entry point (translational alignment) and then alignment to the desired needle insertion angle is performed using a remote center of rotation principle (rotational alignment). There are two possible configurations of the aiming device. - Instrument adapter	The device description is the same.

	mounted either on the ceiling of the CT room or on the visualization /elaboration unit All the tools in contact both with the skin of the patient and with the surgical instruments are sterile disposable.	clamp with trackable marker shield: As an alternative to the aiming device, trackable markershields can be attached directly to rigid needles by means of an instrument adapter. Calibration of the needle geometry is performed with a calibration unit supplied by CAScination. - CAS-One IR software: The software provides the step-by-step workflow assistance for needle navigation. It provides a means for users to precisely plan a single or multiple needle trajectories, navigate a needle to this exact position and validate the inserted needle's position to the planned position.	
Intended Use	SIRIO H3 is a user controlled, stereotactic accessory intended to assist in planning, navigation and manual advancement of one or more instruments, as well as in verification of instrument position and performance during Computed Tomography (CT) guided procedures. SIRIO H3 is indicated for use with rigid straight instruments such as needles and probes used in CT guided interventional procedures performed by physicians trained for CT procedures.	CAS-One IR is a user controlled, stereotactic accessory intended to assist in planning, navigation and manual advancement of one or more instruments, as well as in verification of instrument position and performance during Computed Tomography (CT) guided procedures. In planning, the desired needle configuration and performance is defined relative to the target anatomy. In navigation, the instrument position is displayed relative to the patient and guidance for needle alignment is provided while respiratory levels are monitored.	Equivalent

		In verification, the achieved instrument configuration and performance are displayed relative to the previously defined plan through an overlay of the pre- and post-treatment image data.	
Electrical Safety	IEC 60601-1:2005	IEC 60601-1:2005/A1 2012	
EMC	IEC 60601-1-2:2007	IEC 60601-1-2:2007	Equivalent
Procedure planning	Yes	Yes	Equivalent
Navigation	Yes	Yes	Equivalent
Respiratory motion control	Yes	Yes	Equivalent
Physician Intra-interventional verification	Yes	Yes	Equivalent
Interventional instrument compatibility	Yes	Yes	Equivalent
Sterilization	Yes - ETO	Yes - ETO	Both disposable components are supplied sterile.
Single use disposables	Y	Y	Equivalent
Shelf life	5 years	Not indicated in summary	Expiry date is on the product label
Packaging	Tyvek / Poly pouch	Tyvek / Poly pouch	Equivalent
Materials	Biocompatible	Biocompatible	Equivalent

Conclusion

The products are substantially equivalent as the indications for use are the same, the clinical application is the same, the materials are equivalent, the dimensions are equivalent and the tested product performance attributes are equivalent.