IMACTIS® SAS
℅ Mady Batailh
Quality Manager
5 avenue du Grand Sablon
38700 La Tronche
FRANCE

April 24, 2018

Re: K162314
Trade/Device Name: IMACTIS CT-NAVIGATION system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: April 12, 2018
Received: April 16, 2018

Dear Mady Batailh:

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,

Michael D. O'Hara For

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K162314

Device Name
IMACTIS® CT-NAVIGATION system

Indications for Use *(Describe)*
The IMACTIS® CT-NAVIGATION system is used with linear instruments including but not limited to biopsy needle, aspiration needle, anesthesia needle, ablation needle.
The system supports a workflow based on automated image registration of spatial mapping from image space to physical space.
The system is intended for intra-operative guidance during percutaneous interventional procedure. It is intended for use by trained physicians in clinical intervention and for structures where imaging is currently used for visualizing such procedures.
The system is not intended for guidance for the head, neck, central nervous system and central circulatory system (heart included).

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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Traditional 510(k) Premarket Notification for IMACTIS® CT-NAVIGATION system

510(k) SUMMARY

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

Date Prepared: October, 4th 2017.

Owner's information:

IMACTIS® SAS
5 avenue du Grand Sablon
38700 LA TRONCHE - FRANCE
Phone: +334 76 54 95 40
Fax: +334 76 54 95 61

Contact person:

Mady Batailh
Phone: +33 4 76 54 95 40
Email: quality@imactis.com

Device information:

Trade name:	IMACTIS® CT-NAVIGATION system
Common name:	CT stereotactic accessory
Classification name:	Computed tomography x-ray system (21 CFR 892.1750)
Product code:	JAK
Class:	II
Panel:	Radiology devices

Legally-marketed predicate device:

Manufacturer	System Name	510(k) number	Product code
EDDA-technology	IQQA® Guide	K151414	JAK

Device Description:
The IMACTIS® CT-NAVIGATION system consists of a navigation station, specific software and a dedicated instrumentation set used in an interventional radiology room during percutaneous interventional radiological procedures performed under Computed Tomography.

Intended Use

The IMACTIS® CT-NAVIGATION system is a stereotaxic accessory for Computed Tomography systems. It displays simulated image of interventional instrument on a computer monitor screen that also shows images of the targeted organ(s) and the current and the projected future path of the interventional instrument.

Indications for use

The IMACTIS® CT-NAVIGATION system is used with linear instruments including but not limited to biopsy needle, aspiration needle, anesthesia needle, ablation needle.
The system supports a workflow based on automated image registration of spatial mapping from image space to physical space.

The system is intended for intra-operative guidance during percutaneous interventional procedure. It is intended for use by trained physicians in clinical intervention and for structures where imaging is currently used for visualizing such procedures.

The system is not intended for guidance for the head, neck, central nervous system and central circulatory system (heart included).

Summary of technological characteristics:

Item	IMACTIS® CT-NAVIGATION system	IQQA® Guide	SE
Tracking technology	Electromagnetic tracking technology	Same	YES
Computer Hardware configuration	Standard PC hardware	Same	YES
Used by	Trained physicians	Same	
User Interface	A graphical user interface to interact with the software	Same	YES
Patient imaging display during intervention	Use of acquired patient imaging for anatomy structure: - CT during intervention - Previously acquired CT	Use of acquired patient imaging for anatomy structure: -CT during intervention -CT pre-procedural Previously acquired CT, MR Ultrasound during intervention when available	YES
Combined Display	Combine the display of simulated instrument and display of patient imaging/anatomy model	Same	YES
Clinical environment to be used in	Used in clinical interventions and for anatomical structure where imaging is currently used for visualizing such procedures	Same	YES

Table 2: Summary of technological characteristics

Testing Information and performance:

The design of the device, including software, was realized according to internal design controls procedures to ensure that specified design requirements are met.

Non clinical testing

The IMACTIS® CT-NAVIGATION system was tested for electromagnetic compatibility and electrical safety according to the IEC 60601-1 and IEC 60601-1-2 standards.

Biocompatibility testing was performed on components according to ISO10993 standards.

Sterility of components delivered sterile was tested according to ISO11737 and ISO11607 standards.

CT imaging requirements for the IMACTIS® CT-NAVIGATION system were challenged during the verification phase of the design process using 2 CT-scan series resolutions:

- First resolution corresponds to an axial image resolution of 0.5mm/pixel and a spacing of 1mm between slices

- Second resolution corresponds to the worst accepted case, an axial image resolution of 1mm/pixel (corresponds to a field of view of 512mm) and a spacing of 2mm between images.

The verification testing demonstrates that the IMACTIS® CT-NAVIGATION system performances are maintained in both cases.

Regarding the system accuracy performance on the complete measurement chain (including localization system, calibration and registration accuracy), the IMACTIS® CT-NAVIGATION system was tested in rigid conditions during the verification phase of the design process, on a dedicated test bench. This bench has cylindrical holes at different positions and with different angles. A needle tool, localized by the navigation system, is positioned in those cylindrical holes. For each cylindrical hole, the accuracy is computed as the difference between the known position of the cylindrical hole and the position measured by the medical device. The system accuracy is always smaller than 2° and 2 mm.

While comparing the results of the predicate device and the results of the submitted device as described above, we conclude that the IMACTIS® CT-NAVIGATION system is substantially equivalent to the predicate device in terms of accuracy in rigid conditions.

Clinical testing

Additionally, a clinical testing on patients was conducted with the IMACTIS® CT-NAVIGATION system to provide feedback on the intended use and validate major functionalities by physicians. The system accuracy results on the complete measurement chain was collected on 60 patients for which the intervention was done with IMACTIS® CT-NAVIGATION system. As an information, during a clinical testing, the achieved accuracy of the IMACTIS® CT-NAVIGATION system (using the convention Median [P16%; P84%]) was of 3.8 mm [2.1; 9.9] in Per Protocol and of 4.1 mm [2.1; 11.7] in Intention To Treat.

Regarding system registration performance of the predicate device, and the IMACTIS® CT-NAVIGATION system accuracy performance measured on the complete measurement chain, the IMACTIS® CT-NAVIGATION system is substantially equivalent to the predicate device

Testing drawn from the nonclinical and clinical tests demonstrate that the actual device performance is substantially equivalent to the predicate device performance. The IMACTIS® CT-NAVIGATION system is as safe, as effective and performs as well as the legally marketed device.

Conclusion on substantial equivalence:

The IMACTIS® CT-NAVIGATION system has the same intended use as the predicate device IQQA® Guide. It is substantially equivalent in the areas of technical characteristics, principles of operations and functional features. It does not raise any new questions of safety and effectiveness.

The IMACTIS® CT-NAVIGATION system is substantially equivalent to IQQA® Guide.