March 13, 2024

Cascination AG
% Andreas Meschberger
Senior Regulatory & Clinical Affairs Manager
Steigerhubelstrasse 3
BERN, 3008
SWITZERLAND

Re: K232022
Trade/Device Name: CAS-One IR
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 14, 2024
Received: February 14, 2024

Dear Andreas Meschberger:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Smita Kakar

Lu Jiang
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232022

Device Name
CAS-One IR

Indications for Use *(Describe)*
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.
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.
CAS-One IR 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 intended to be used for patients older than 18 years and eligible for CT-guided percutaneous interventions.

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.

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CASCINATION

Steigerhubelstrasse 3
CH-3008 Bern
Switzerland

510(K) SUMMARY

K232022

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

I. SUBMITTER

Manufacturer: CASCINATION AG
Steigerhubelstrasse 3
CH-3008 Bern
Switzerland
Tel: +41 31 306 26 26
Contact Person: Andreas Meschberger
Senior Regulatory & Clinical Affairs Manager
Date Prepared: March 08, 2024

II. SUBJECT DEVICE

Device Name:	CAS-One IR
Classification Name:	Computed tomography x-ray system
Regulation:	892.1750
Common Name:	System, X-Ray, Tomography, Computed
Regulatory Class:	Class II
Product Code:	JAK

The Subject Device is an updated version of the Predicate Device.

III. PREDICATE DEVICE

Primary Predicate Device

Company:	CASCINATION AG, Steigerhubelstrasse 3, CH-3008 Bern, Switzerland
Device name:	CAS-One IR
510(k) number:	K152473
Classification Name:	Computed tomography x-ray system
Regulation:	892.1750
Common Name:	System, X-Ray, Tomography, Computed
Regulatory Class:	Class II
Product Code:	JAK

IV. INDICATIONS FOR USE

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.

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.

CAS-One IR 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 intended to be used for patients older than 18 years and eligible for CT-guided percutaneous interventions.

V. DEVICE DESCRIPTION

The system consists of the following 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.
- Instruments: The instrument set comprises a guide arm, aiming device and a navigational pointer that are connected to each other and assist the user in aligning and positioning a needle trajectory relative to the patient. After positioning the aiming device using the guide arm, the

aiming device is aligned with respect to the desired entry point (translational alignment) and rotationally oriented to the desired insertion angle.

- 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.

VI. SUBSTANTIAL EQUIVALENCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

Item	Subject Device (CAS-One IR)	Predicate Device (CAS-One IR) K152473	Conclusion
Regulation Number	Regulation Number: 21 CFR 892.1750 Product Code: JAK	Regulation Number: 21 CFR 892.1750 Product Code: JAK	⇨ Same Both the subject and predicate devices have the same product code and regulation number

Item	Subject Device (CAS-One IR)	Predicate Device (CAS-One IR) K152473	Conclusion
Indications For Use Statement	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. 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. CAS-One IR 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 intended to be used for patients older than 18 years and eligible for CT-guided percutaneous interventions.	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. 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. CAS-One IR 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.	⇨ Same, but more specific Both the subject and predicate devices have the same general indications for use statement and the subject device has an additional specificity regarding the target population
User	physicians trained for interventional CT procedures	physicians trained for interventional CT procedures	⇨ Same Both the subject and predicate devices have the same user

Item	Subject Device (CAS-One IR)	Predicate Device (CAS-One IR) K152473	Conclusion
System			
System	Consists of: • Platform • Pointer, Aiming device, Guide Arm • CAS-One IR software	Consists of: • Platform • Pointer, Aiming device, Guide Arm • CAS-One IR software	⇨ Same There was no change in the system concept
Compatibility	The system is compatible with needle-shaped devices used in percutaneous interventional procedures that have the following physical properties: • Cylindrical, straight shape • Design that allows the placement of instruments in the Guide	The system is compatible with needle-shaped devices used in percutaneous interventional procedures that have the following physical properties: • Cylindrical, straight shape • Design that allows the placement of instruments in the Guide	⇨ Same There was no change in the system compatibility
Hardware			
Navigation Platform	Same: Camera, Rack, Screen Arms, Camera Arms Updated: Touch screens, Graphic Cards, Mother board and Power Supplier	Same: Camera, Rack, Screen Arms, Camera Arms Predicate: Touch screens, Graphic Cards, Mother board and Power Supplier	⇨ Same The updated components have the same technical principles and just represent an updated technical state. The parts are covered by the Electrical Safety and EMC Testing, and System Validation
Pointer (Aiming Insert and Marker Shield), Aiming Device, Guide Arm.	Surgical Stainless Steel 1.4301 & 1.4305 Slight mechanical design improvements.	Surgical Stainless Steel 1.4301	⇨ Same Both devices use a surgical stainless steel of a slightly different type. Minor mechanical design improvements.
Patient Fixation	Vacuum cushion on top of carbon baseplate.	Vacuum cushion on top of carbon baseplate.	⇨ Same
Energy Source	110-230V, 50-60Hz, single phase	110-230V, 50-60Hz, single phase	⇨ Same

Item	Subject Device (CAS-One IR)	Predicate Device (CAS-One IR) K152473	Conclusion
Software			
Operating System	Windows 10	Windows 7	⇨ Same Both devices run on Microsoft Windows, installed on the platform. Programming language and software architecture remain the same. Full Software V&V has been executed and passed
Image datasets	DICOM file format: • CT or MRI image modality	DICOM file format: • CT image modality	⇨ Same The subject device allows to import MRI images, but they must also comply to the DICOM standard
Data Management DICOM Viewer	Function to import image datasets. Function to view, pan, zoom, adjust brightness and insensitivity, and carry out measurements in image data and to overlay image data	Function to import image datasets. Function to view, pan, zoom, adjust brightness and insensitivity, and carry out measurements in image data and to overlay image data	⇨ Same
Module Plan	Trajectory Planning Single / Multiple needles Display of manufacturer ablation parameters Point-based image fusion CT to CT or MR. Segmentation of organs (liver tissue, portal vein, hepatic vein, liver lesions, kidney tissue, lung tissue, and lung airway)	Trajectory Planning Single / Multiple needles Display of manufacturer ablation parameters Point-based image fusion CT to CT	⇨ Different Technological characteristic “Segmentation of organs and lesions” which does not raise any concern about safety and effectiveness. The Point-based registration MRI to CT images of the subject device is similar to the Point-based registration CT to CT images of the predicate device and does not represent a technological difference

Item	Subject Device (CAS-One IR)	Predicate Device (CAS-One IR) K152473	Conclusion
Navigation	Module Name “Place” Supports Instrument Guide	Module Name “Navigation” Supports Instrument Guide and Freehand	⇨ Same The module was renamed but the functionality remains the same The optional support of freehand navigation has been discontinued in the subject device
Verify (Control Scan)	Verify (Control Scan) Instrument Detection	Verify (Control Scan)	⇨ Different Technological characteristic “Instrument Detection” which does not raise any concern about safety and effectiveness.
Verification	Module “Assess” Manual review of planning and validation images (toggle visibility) AblaSure® Ablation Assessment (for liver lesions)	Module “Assess” Manual review of planning and validation images (toggle visibility)	⇨ Different Technological characteristic “AblaSure® Ablation Assessment” which does not raise any concern about safety and effectiveness.
Performance Testing			
Performance Testing	Software design verification and validation and documentation (the software for this device was considered a “moderate” level of concern.) Formal Internal Testing Standards Electrical Safety according to ANSI AAMI ES60601-1 Electromagnetic Compatibility according to IEC 60601-1-2 Testing of Segmentation Algorithms according to internal Testing Standards	Software design verification and validation and documentation (the software for this device was considered a “moderate” level of concern.) Formal Internal Testing Standards Electrical Safety according to ANSI AAMI ES60601-1 Electromagnetic Compatibility according to IEC 60601-1-2 Biocompatibility and Sterilization	⇨ Same The performance testing for the subject device are the same, additional tests were carried out for the segmentation algorithms, while testing for biocompatibility and sterilization were not required to the similar design and materials to the predicate device

Substantial Equivalence Discussion

Both the Subject Device and the Predicate Device have the same Intended Use. The Subject Device is an updated version of the Predicate Device. The differences between the Subject and Predicate Device are: Incremental improvements to the hardware (updated mainboard, GPU, and touchscreens on the platform; mechanical improvements to the pointer, aiming device, and guide arm), and Software Changes (update Operating System, incremental improvements, addition of segmentation functions for tumor and ablation area)
The subject device introduces seven new software functions which are considered to have the same technological characteristics as the predicate device because similar software functions are included in the predicate device.
The subject device has three different technological characteristics compared to the predicate device: Segmentation of organs and liver lesions, Instrument Detection, AblaSure® Ablation Assessment (for liver lesions). All three different technological characteristics are related to Software Functions.
Software Validation has been carried out for all functions. Specific Non-Clinical Performance Testing has been carried out for the segmentation algorithms. The instructions for use include warnings for the limitations of the segmentation algorithms.
It has been demonstrated that the technological differences do not adversely affect the safety and effectiveness of the subject device. No questions for safety and effectiveness were raised.
Therefore, we can conclude that no technological differences, that may adversely affect the safety and effectiveness, have been identified between the subject and predicate device.

Conclusion - Substantial Equivalence Discussion:

The subject device is substantially equivalent to the predicate device with regard to intended use, safety, and effectiveness. This conclusion is based upon a comparison of intended use, technological characteristics, and non-clinical performance testing.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

Not Applicable. The subject device has similar material properties, and it was evaluated there is no effect to the biocompatibility properties of the subject device.

Electrical safety and electromagnetic compatibility (EMC)

The subject device was tested for electrical safety (ANSI AAMI ES60601-1) and electromagnetic compatibility (ANSI AAMI IEC 60601-1-2).

Mechanical and Acoustic Testing

Not Applicable to the subject device.

Software Verification and Validation Testing

Software verification and validation testing were provided to demonstrate safety and effectiveness of the subject device. Software validation and documentation was prepared according to the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” (May 11, 2005).

This includes a hazard analysis, and the potential hazards have been classified as a moderate level of concern similar to the predicate device.

Algorithm validation

Test protocols were systematically executed to assess the performance of the algorithms. Algorithmic validation procedures involved comparisons with ground truth data annotated by personnel considered expert in the domain.

The segmentation algorithms of organs, hepatic veins, and lesions were validated by comparing the mean DICE coefficient with state-of-the-art algorithms. Defined acceptance criteria for mean DICE (Liver: 0.9, Tumor: 0.8, Effective Treatment Volume: 0.8, Kidney: 0.85, Lung: 0.9) and mean centerline DICE (Liver-Vessels: 0.6) were passed.

For instrument detection algorithms, the reliability was gauged by analysing the proximity between ground truth positions and the positions identified by the algorithm.

These validation efforts provide a robust foundation for asserting the accuracy and effectiveness of the algorithms in the context of their application in medical settings.

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Clinical Studies

Clinical testing was not required to demonstrate the safety and effectiveness of the device. This conclusion is based upon a comparison of intended use, technological characteristics, and non-clinical performance data (Software Verification and Validation Testing, and Internal Test Standards).

VIII. CONCLUSIONS

The subject device is substantially equivalent to the predicate device with regard to device performance. This conclusion is based upon a comparison of the intended use, technological characteristics, and benchtop testing.