



September 29, 2026

Cascination AG
% Philip Frost
Regulatory and Clinical Affairs Specialist
Steigerhubelstrasse 3
BERN, 3008
SWITZERLAND

Re: K261225
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: August 28, 2026
Received: August 28, 2026

Dear Philip Frost:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,



Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261225

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Please provide the device trade name(s).

?

CAS-One IR

Please provide your Indications for Use below.

?

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.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(K) SUMMARY – K261225

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

I. SUBMITTER

Manufacturer: CASCINATION AG
Steigerhubelstrasse 3
3008 Bern
Switzerland
Tel: +41 31 306 26 26

Contact Person: Philip Frost
Regulatory and Clinical Affairs Specialist

Date Prepared: September 25, 2026

II. SUBJECT DEVICE

Device Name: CAS-One IR

Parent Device: CAS-One IR Software

Accessories: CAS-One IR Platform A, CAS-One IR Baseplate A, CAS-One IR Cushion A, CAS-One IR Accessory Tray A, CAS-One IR Aiming Device A, CAS-One IR Guide Arm A, CAS-One IR Pointer A, CAS-One IR Consumable Set General

Common Name: System, X-Ray, Tomography, Computed

Classification Name: Computed Tomography X-Ray System

Regulation: 892.1750

Regulatory Class: Class II

Product Code: JAK

CAS-One IR is an updated version of the Predicate Device (K232022) and is an image-guided system for CT-guided percutaneous interventions. The medical functionality (planning, guidance, and verification) is provided by the Parent Device, CAS-One IR Software. The Accessories support the Parent Device in achieving this functionality. The CAS-One IR Software and the Accessories below are separate finished devices, each with their own labeling (see Device Description).

Name	REF
CAS-One IR Software	20016
CAS-One IR Platform A	10006
CAS-One IR Baseplate A	30238
CAS-One IR Cushion A	30128
CAS-One IR Accessory Tray A	30007
CAS-One IR Aiming Device A	30085
CAS-One IR Guide Arm A	30026
CAS-One IR Pointer A	30027
CAS-One IR Consumable Set General	50002

The overall intended use, functionality, use context, and clinical workflow remain unchanged relative to 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: [K232022](#)
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

CAS-One IR comprises the CAS-One IR Software (Parent Device), and eight Accessories. All Accessories and components are intended to be used together as part of the CAS-One IR procedure, and none performs a standalone medical function independent of the CAS-One IR Software.

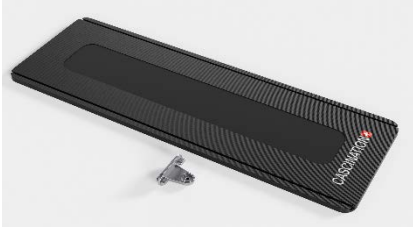
The CAS-One IR Software is a medical device software from which the medical purpose of the CAS-One IR procedure is derived, while the hardware Accessories enable tracking, positioning, instrument alignment, and patient stabilization, and consumable Accessories support the procedural workflow.

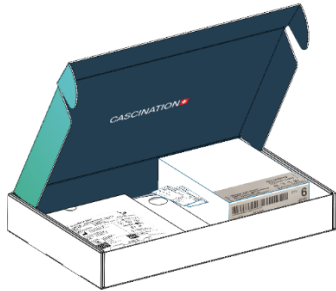
Each Accessory listed in Table 1 is a finished device, individually labeled, intended to support, supplement, and/or augment the performance of the Parent Device, the CAS-One IR Software, during image-guided, percutaneous interventions.

None of the Accessories has a medical purpose independent of the CAS-One IR Software.

Table 1

Accessories for the CAS-One IR Software

Accessory Name	Description	Reference Image
CAS-One IR Platform A:	The CAS-One IR Platform A provides computing, data storage and exchange, display, user input, and stereophotogrammetric (optical) position sensing; the CAS-One IR Software runs on the Platform.	
CAS-One IR Baseplate A:	The CAS-One IR Baseplate A provides interfaces for patient immobilization and for attachment of instruments.	
CAS-One IR Cushion A:	The CAS-One IR Cushion A immobilizes the patient.	

Accessory Name	Description	Reference Image
CAS-One IR Accessory Tray A:	The CAS-One IR Accessory Tray contains and holds CASCINATION instruments during cleaning, disinfection, steam sterilization, storage, and aseptic presentation.	 A black plastic tray with a silver metal mesh insert. The mesh insert has several slots for holding instruments.
CAS-One IR Aiming Device A:	The CAS-One IR Aiming Device A adjusts the orientation of an instrument's trajectory and provides physical guidance for instruments.	 A complex metal device with multiple adjustment knobs and a central clamping mechanism for holding an instrument.
CAS-One IR Guide Arm A:	The CAS-One IR Guide Arm A holds and stabilizes instruments.	 A long, thin metal arm with a central adjustment knob and two end pieces for holding instruments.
CAS-One IR Pointer A:	The CAS-One IR Pointer A is an optically tracked tool that enables determination of its pose for alignment with the planned trajectory.	 A Y-shaped metal tool with three arms, each ending in a small tip for optical tracking.
CAS-One IR Consumable Set General:	The CAS-One IR Consumable Set General contains consumable items supporting the CAS-One IR procedure workflow.	 An open white box with a blue lid. The lid has the CASCINATION logo. Inside the box are several white and blue packets, likely containing consumables.

VI. SUBSTANTIAL EQUIVALENCE

The following characteristics were compared between the Subject Device and the Predicate Device in order to demonstrate substantial equivalence (Table 2).

Table 2

Summary of the Substantial Equivalence (SE) Comparison to Predicate Device

Item	Predicate Device (K232022)	Subject Device (K261225)	SE Conclusion
Intended Use			
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. CAS-One IR is intended to be used for patients older than 18 years and eligible for CT-guided percutaneous interventions.	Same No changes.

Item	Predicate Device (K232022)	Subject Device (K261225)	SE Conclusion
User	Physicians trained for interventional CT procedures	Physicians trained for interventional CT procedures	Same No changes.
Device Structure			
Device Structure	CAS-One IR, consisting of the CAS-One IR Software, its hardware components and consumables used exclusively together for the CAS-One IR procedure.	CAS-One IR, consisting of the CAS-One IR Software (Parent Device) and eight separately labeled and packaged Accessories (CAS-One IR Platform A, Baseplate A, Cushion A, Accessory Tray A, Aiming Device A, Guide Arm A, Pointer A, and Consumable Set General) used exclusively together for the CAS-One IR procedure.	Substantially equivalent Same software, hardware, and consumables used together for the same procedure. Only the regulatory structure changed: hardware and consumables are now separately labeled Accessories to the CAS-One IR Software, with no independent medical purpose. No impact on intended use, functionality, safety, or performance.
Technical Characteristics			
CAS-One IR Software			
Compatible Operating System(s)	Windows 10 IoT Enterprise LTSC.	Windows 10 IoT Enterprise LTSC, or Windows 11 IoT Enterprise LTSC.	Substantially equivalent Upgrade within the Microsoft Windows family. The change does not affect the intended use or fundamental functionality. Cybersecurity of the subject operating system was re-assessed and verified for Windows 11 IoT Enterprise LTSC (see Performance Data, Cybersecurity).
Image datasets	DICOM file format: • CT or MRI image modality	DICOM file format: • CT or MRI image modality	Same No changes.
Data Management	Functionality to import image datasets from USB and LAN.	Functionality to import image datasets from USB and LAN.	Same No changes.

Item	Predicate Device (K232022)	Subject Device (K261225)	SE Conclusion
DICOM Viewer	- o Functionality to view, pan, zoom, adjust brightness and intensity, and carry out measurements in image data and to overlay image data - o Standard perspectives (axial, coronal, sagittal) - o Oblique perspectives aligned with the planned trajectory - o Toggle (show/hide) of individual annotations and trajectories	- o Functionality to view, pan, zoom, adjust brightness and intensity, and carry out measurements in image data and to overlay image data - o Standard perspectives (axial, coronal, sagittal) - o Oblique perspectives aligned with the planned trajectory - o Toggle (show/hide) of individual annotations and trajectories - o Adjustable oblique MPR perspectives - o Toggle (show/hide) of all annotations and trajectories	Substantially equivalent The adjustable oblique MPR perspectives extend the oblique viewing already available in the Predicate Device to the MPR views. The show/hide-all toggle combines the existing individual toggles into a single action. Both are established DICOM-viewing functions that display the same image data without modification. They introduce no new clinical output or interpretive task and have no impact on core functionality, safety, or performance.
Planning and Fusion	- o Trajectory Planning - o Single / Multiple needles - o Display of manufacturer ablation parameters - o Point-based image fusion CT to CT or MR - o Real time visualization of patient markers	- o Trajectory Planning - o Single / Multiple needles - o Display of manufacturer ablation parameters - o Point-based image fusion CT to CT or MR - o Real-time and static visualization of patient markers - o Patient-Marker Assessment Support	Substantially equivalent Minor visualization and workflow refinements; no impact on core functionality, safety, or performance.
Organ segmentation	Segmentation of: - o liver tissue, - o portal vein, - o hepatic vein, - o kidney tissue, - o lung tissue, - o lung airway,	Segmentation of: - o liver tissue, - o portal vein, - o hepatic vein, - o kidney tissue, - o lung tissue, - o lung airway, - o gallbladder, - o heart, - o spleen, - o digestive system, - o bone and cartilage	Substantially equivalent The Subject Device uses the same segmentation algorithm and was validated using the same testing method as the Predicate Device. The technological change is that additional organs are being segmented as an output.

Item	Predicate Device (K232022)	Subject Device (K261225)	SE Conclusion
Lesion segmentation	Segmentation of liver lesions	Segmentation of liver lesions Sub-capsular lesion support for liver	Substantially equivalent Minor segmentation improvement using the same machine learning algorithm and development process - no new functionality nor modification of the nature of the output. Sub-capsular lesion support refines margin representation using existing segmentation outputs without modifying underlying algorithms.
Placement	Instrument placement support.	Instrument placement support.	Same No changes.
Verification	Instrument Detection.	Instrument Detection.	Same No changes.
Assessment	Manual review of planning and validation images (toggle visibility) AblaSure® Assessment: - o Effective treatment volume for the liver - o Tumor coverage for the liver - o Margin coverage for the liver	Manual review of planning and validation images (toggle visibility) AblaSure® Assessment: - o Effective treatment volume for the liver - o Tumor coverage for the liver - o Margin coverage for the liver Re-ablation workflow for the liver	Substantially equivalent Minor segmentation improvement using the same machine learning algorithm and development process - no new functionality nor modification of the nature of the output. Re-ablation for liver introduces no new capability. The same result was already achievable with the Predicate Device by starting a new case from the existing image data and planning a new trajectory. The re-ablation workflow only carries the existing data and plan forward directly, removing the manual re-setup steps. It produces no new output and does not change the intended use, functionality, safety, or performance.

Item	Predicate Device (K232022)	Subject Device (K261225)	SE Conclusion
Accessories			
CAS-One IR Platform			
General	Dimensions: - Height: 2.0 m - Width: 0.7 m - Depth: 1.2 m Weight: 85 kg Type: Mobile equipment Operating mode: Continuous use Insulation class: 1 Ingress protection: IP20	Dimensions: - Height: 2.0 m - Width: 0.7 m - Depth: 1.2 m Weight: 85 kg Type: Mobile equipment Operating mode: Continuous use Insulation class: 1 Ingress protection: IP20	Same No changes.
Installed Operating system	Windows 10 IoT Enterprise LTSC	Windows 11 IoT Enterprise LTSC	Substantially equivalent - Same OS family and edition: Windows NT, IoT Enterprise LTSC. - Same architecture: x64 (64-bit). - Same application binary interface (ABI): Win32 API, PE executable format and x64 calling convention. The CAS-One IR 4.3.0 binaries run unchanged on both. - Same servicing model: LTSC, with long-term, security-only updates and no feature updates. - Differences limited to: a newer OS build, updated drivers, and equal or stronger security defaults.
Power supply	Power: 600 W Input voltage: 85-264 Input frequency: 47-440 Hz Certifications: IEC60601-1 3rd edition, MTBF: > 320,307 hours	Power: 600 W Input voltage: 85-264 Input frequency: 47-440 Hz Certifications: IEC60601-1 3rd edition MTBF: > 400,000 hours	Substantially equivalent Integration of new AC/DC module led to new IEC 60601-1 and IEC 60601-1-2 testing (according CB Scheme by external accredited lab) No impact on core functionality otherwise.
I/O Ports	1 x Ethernet 1Gbit/s 1 x USB-A(USB3.0)	1 x Ethernet 1Gbit/s 1 x USB-A(USB3.2)	Substantially equivalent USB 3.2 is backwards compatible, Ethernet speed is the same.

Item	Predicate Device (K232022)	Subject Device (K261225)	SE Conclusion
Camera	Type: Stereophotogrammetric (optical) position sensing Model: NDI Polaris Vicra Volumetric accuracy (RMS / 95% CI): 0.25 mm / 0.5 mm Max. frame rate: 20 Hz Measurement volume: depth 1420 mm, width 938 mm, height 887 mm Interface / power: USB (serial API) Weight: 0.8 kg	Type: Stereophotogrammetric (optical) position sensing Model: NDI Polaris Lyra Position Sensor NB Volumetric accuracy (RMS / 95% CI): 0.20 mm / 0.40 mm Max. frame rate: 60 Hz Measurement volume: depth 1420 mm, width 1190 mm, height 1080 mm Interface / power: Ethernet with PoE (internal PoE injector) Weight: 0.8 kg	Substantially equivalent Different tracking-camera model with higher frame rate, larger measurement volume and improved volumetric accuracy. Navigation accuracy was re-assessed for the subject camera and shown non-inferior to the predicate camera.
Touch screens	Model: 2 × ACL OR-MD 24 Resolution: 1920 × 1200	Model: 2 × ACL OR-MD 24 Resolution: 1920 × 1200	Substantially equivalent Touch screens upgraded to current-generation models with the same display and touch-input functions. Platform re-tested to IEC 60601-1 and IEC 60601-1-2 under the CB Scheme (see Performance Data). No impact on intended use, functionality, safety, or performance.
Control box	Mainboard platform: Mini-ITX, Intel Q87, LGA1150 Memory support: up to 16 GB DDR3/DDR3L 1333/1600 TPM: TPM 1.2 (optional) CPU cores / threads: 4 / 8 CPU clock: 3.1 GHz base / 3.9 GHz turbo CPU cache / TDP: 8 MB L3 / 65 W GPU CUDA cores / memory: 1280 / 5 GB GDDR5X GPU bandwidth / interface: up to 200 GB/s / PCIe 3.0 x16 GPU max power: 75 W RAM: 16 GB DDR3 Storage: 1 TB mSATA SSD (SATA III 6 Gb/s)	Mainboard platform: Mini-ITX, LGA1700, R680E/Q670E/H610E chipset Memory support: up to 64 GB DDR4-3200, ECC or non-ECC TPM: TPM 2.0 (onboard) CPU cores / threads: 12 (8P + 4E) / 20 CPU clock: P-cores 1.4-4.6 GHz, E-cores 1.0-3.4 GHz CPU cache / TDP: 25 MB Smart Cache / 35 W GPU CUDA cores / memory: 2816 / 16 GB GDDR6 ECC GPU bandwidth / interface: 224 GB/s / PCIe 4.0 x8 GPU max power: 70 W RAM: 32 GB DDR4 Storage: 256 GB (OS) + 2 TB RAID 1 (data and application)	Substantially equivalent Computing components upgraded to current-generation models with equal or higher performance. Platform re-tested to IEC 60601-1 and IEC 60601-1-2 under the CB Scheme (see Performance Data). No impact on intended use, functionality, safety, or performance.

Item	Predicate Device (K232022)	Subject Device (K261225)	SE Conclusion
Frame and housing	Powder Coated Aluminium Frame 4x Caster with brakes 2x Mechanical monitor arms 1x Mechanical camera arm	Powder Coated Aluminium Frame 4x Caster with brakes 2x Mechanical monitor arms 1x Mechanical camera arm	Substantially equivalent Housing color change only; no impact on intended use, functionality, safety, or performance.
CAS-One IR Baseplate A			
CAS-One IR Baseplate A	Provides interfaces for patient immobilization and for attachment of instruments. Dimensions: ~1500 × 500 × 20 mm Weight: 7 kg Material: Polymethacrylimide foam, carbon fiber, glass fiber reinforced polyamide	Provides interfaces for patient immobilization and for attachment of instruments. Dimensions: ~1500 × 500 × 20 mm Weight: 7 kg Material: Polymethacrylimide foam, carbon fiber, glass fiber reinforced polyamide	Substantially equivalent Label change. No impact on intended use, functionality, safety, or performance. The device has no patient contact.
Adapter	Material: Stainless steel	Material: Stainless steel	Same No change.
CAS-One IR Cushion A			
CAS-One IR Cushion A	Cushion that conforms to the patient and, once air is evacuated, maintains a rigid shape to immobilize the patient. Dimensions: ~2000 × 700 × 70mm Weight: ~4.5 kg Materials: sealed airtight bag with plastic pellets; valve; loop tape	Cushion that conforms to the patient and, once air is evacuated, maintains a rigid shape to immobilize the patient. Dimensions: ~2000 × 700 × 70mm Weight: ~4.5 kg Materials: sealed airtight bag with plastic pellets; valve; loop tape	Substantially equivalent Label change from system level to device level. No impact on intended use, functionality, safety, or performance. The device has no patient contact.
CAS-One IR Accessory Tray A			
CAS-One IR Accessory Tray A	Reusable tray that holds CASCINATION instruments in place during cleaning, disinfection, steam sterilization, storage, and aseptic presentation. Dimensions: 406 × 253 × 70mm Materials: stainless steel, silicone, polypropylene, PPSU	Reusable tray that holds CASCINATION instruments in place during cleaning, disinfection, steam sterilization, storage, and aseptic presentation. Dimensions: 390 × 230 × 93mm Materials: stainless steel, silicone, polypropylene, PPSU	Substantially equivalent No impact on intended use, functionality, safety, or performance. The device has no patient contact.

Item	Predicate Device (K232022)	Subject Device (K261225)	SE Conclusion
CAS-One IR Aiming Device A			
CAS-One IR Aiming Device A	Mechanical guide that holds the instrument and allows fine adjustment of its trajectory Arm Connection: Rigid connection to the guide arm Material: Stainless steel, titanium alloy, PEEK Adjustment axes: Two rotational axes with zero-position markings	Mechanical guide that holds the instrument and allows fine adjustment of its trajectory Arm Connection: Rigid connection to the guide arm Material: Stainless steel, titanium alloy, PEEK Adjustment axes: Two rotational axes with zero-position markings	Substantially equivalent Label change from system level to device level. No impact on intended use, functionality, safety, or performance.
CAS-One IR Guide Arm A			
CAS-One IR Guide Arm A	Articulated arm with an optional extender for additional reach that, once its joints are locked, holds a stable position. Dimensions (Arm / Extender): ~436 × 35 × 119 mm / ~183 × 25 × 10 mm Weight (Arm / Extender): ~2 kg / ~0.15 kg Joints: 3, articulated, lockable Materials: stainless steel, aluminium / stainless steel	Articulated arm with an optional extender for additional reach that, once its joints are locked, holds a stable position. Dimensions (Arm / Extender): ~460 × 63 × 90 mm / ~185 × 25 × 28 mm Weight (Arm / Extender): ~1.4 kg / ~0.16 kg Joints: 3, articulated, lockable Materials: stainless steel, aluminium, PEEK / stainless steel, PEEK	Substantially equivalent Same operating principle, 3 lockable joints, central locking handle, interfaces, and extender length as the Predicate Device. Minor design changes only: slightly longer arm, redesigned handle, improved screw retention, and added PEEK guiding sleeves. No impact on intended use, functionality, safety, or performance. The device has no patient contact.
CAS-One IR Pointer A			
CAS-One IR Pointer A	Two-component tracked pointer whose pose is determined for alignment with the planned trajectory. Dimension: ~116 × 84 × 25mm Raw Material: titanium/ stainless steel	Single-component tracked pointer whose pose is determined for alignment with the planned trajectory. Dimension: ~116 × 84 × 25mm Raw Material: stainless steel	Substantially equivalent Same dimensions and marker geometry. Changes are limited to a single-component design instead of two components and a marker array material change from titanium to stainless steel. No impact on intended use, functionality, safety, or performance.
CAS-One IR Consumable Set General			
CAS-One IR Consumable Set General	Consumable components supporting the procedure	Consumable components supporting the procedure	Same No changes.

Item	Predicate Device (K232022)	Subject Device (K261225)	SE Conclusion
Performance Testing			
Performance Testing	- o Software verification and validation ("moderate" level of concern) - o Internal Test Standards - o Segmentation algorithm verification and validation - o Electrical safety (IEC 60601-1) - o Electromagnetic compatibility (IEC 60601-1-2) - o Usability validation	- o Software verification and validation ("moderate" level of concern) - o Internal Test Standards - o Segmentation algorithm verification and validation - o Electrical safety (IEC 60601-1) - o Electromagnetic compatibility (IEC 60601-1-2) - o Usability validation - o Hardware verification and validation (including compatibility, mechanical, environmental, and transport testing)	Substantially equivalent Verification and validation activities were performed in accordance with applicable standards and design control processes and demonstrate safety and effectiveness as compared to predicate.

Substantial Equivalence Discussion:

Intended Use

The Subject Device (CAS-One IR) has the same intended use as the Predicate Device. The Subject Device, together with its Accessories, is an updated version of the Predicate Device and delivers the same clinical functionality and medical purpose. Differences between the Subject and Predicate Device are:

Hardware changes consist only of minor design and material modifications, consolidation of predicate components into individually labeled Accessories, and incremental upgrades to computing or camera components intended to maintain state-of-the-art performance and cybersecurity. These changes do not affect the intended purpose, functionality, safety, or performance of the Subject Device.

Changes to the software consist of user interface enhancements, visualization improvements, workflow restructurings that build directly upon existing capabilities, and an extension of the organ segmentation outputs to additional anatomical structures. The software relies on the same core programming languages, logic, and machine learning algorithms as the Predicate Device. The extended segmentation outputs constitute a difference in technological characteristics, which does not raise different questions of safety and effectiveness, as demonstrated by segmentation validation.

Conclusion

The Subject Device is substantially equivalent to the Predicate Device ([K232022](#)) with respect to intended use and technological characteristics. 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.

i. Software Verification and Validation Testing

Software verification and validation testing were conducted to demonstrate safety and effectiveness of the Subject Device as compared to the predicate. Software documentation was prepared according to the “Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff” (June 14, 2023).

All planned software verification and validation testing were successfully completed, and the testing confirmed that the Subject Device performs as intended and meets all predefined acceptance criteria, thereby demonstrating its safety and effectiveness as compared to the predicate.

o Internal Test Standards

Internal test protocols were executed and documented in test reports to demonstrate navigation accuracy performance. Navigation accuracy was evaluated using a carbon phantom representing patient size, with ground truth geometrical data including trajectory entry points, direction vectors, and single marker positions. Testing was performed under worst-case conditions, comprising a reduced marker configuration (4 of 6 markers visible), a long instrument insertion depth of 225 mm to simulate large patient geometry, and camera tracking positions most distant to the tracking camera.

Testing was conducted for both supported optical tracking cameras (NDI Polaris Vicra and Lyra), with 112 measurements per camera across multiple trajectories. Lateral deviation at the target was defined as the metric of interest, as it is the clinically relevant measure of targeting accuracy, and was assessed against a predefined acceptance threshold.

All acceptance criteria were met for both tracking cameras. Mean lateral deviation was 1.00 mm (SD 0.63 mm) for Lyra and 0.93 mm (SD 0.63 mm) for Vicra. In addition, a paired non-inferiority comparison of Lyra versus Vicra was performed with both cameras mounted co-axially, tracking the same 16 trajectories from the same camera position with 4 of 6 markers visible. The mean paired difference in alignment accuracy was 0.126 mm (SD 0.254 mm), and the upper bound of the one-sided 97.5% confidence interval (0.262 mm) was below the predefined non-inferiority margin of 0.5 mm. The Lyra camera is therefore non-inferior to the Vicra camera.

o Segmentation Validation

Segmentation performance was evaluated using representative clinical datasets acquired across multiple clinical sites, covering multiple anatomical structures. Performance was assessed using Dice similarity coefficients and statistical confidence limits. Predefined acceptance criteria for mean Dice and lower confidence limits were met for all evaluated structures, demonstrating accurate and reliable segmentation performance (Table 3). The segmentation algorithms are based on the same underlying methodological approach as the Predicate Device and exhibit equivalent performance characteristics.

Table 3

Summary – Segmentation Performance

Segmentation Target	Acceptance Criterion (Dice)	Mean Dice
Bone and Cartilage	≥ 0.85	0.91
Gallbladder	≥ 0.85	0.89
Heart	≥ 0.85	0.93
Digestive System	≥ 0.85	0.88
Spleen	≥ 0.85	0.97
Lesion	≥ 0.80	0.86
Effective Treatment Volume	≥ 0.80	0.86
Liver	≥ 0.90	0.95
Liver Vessel (Portal Vein)	≥ 0.60	0.67
Liver Vessel (Hepatic Vein)	≥ 0.60	0.72
Lung (incl. airways, excl. vessels)	≥ 0.90	0.97
Kidney	≥ 0.85	0.88

ii. Hardware Verification and Validation

Verification and validation activities were conducted in accordance with established design control procedures and covered mechanical, functional, environmental, and transport testing representative of distribution conditions. Design verification demonstrated that the device conforms to defined design input requirements through mechanical and functional testing. Device validation demonstrated that the device fulfills user needs and intended use under representative conditions.

- o **Electrical safety (IEC 60601-1)**

The CAS-One IR Platform was tested under the CB Scheme according to IEC 60601-1:2005 + A1:2012 + A2:2020. All applicable clauses of the standard were verified through laboratory testing, including mechanical strength, electrical insulation, protection against electric shock, leakage currents, dielectric strength, and marking and labeling requirements. All tests were conducted by an accredited laboratory using calibrated equipment and documented procedures. The overall result of the CB Scheme type testing was pass.

- o **Electromagnetic compatibility (IEC 60601-1-2)**

The CAS-One IR Platform was tested according to IEC 60601-1-2:2014 + A1:2020 under the CB Scheme. All applicable EMC requirements were evaluated, including emissions (radiated and conducted), immunity to electrostatic discharge, radiated RF fields, electrical fast transients, surges, conducted disturbances, magnetic fields at mains frequency, and voltage dips and interruptions.

Testing was performed by an accredited laboratory using calibrated equipment and standardized setups according to the normative test procedures. The system met the acceptance criteria in all tests. No degradation of performance, functional loss, or unsafe conditions were observed during or after exposure to electromagnetic disturbances. The overall result of the CB Scheme EMC testing according to IEC 60601-1-2:2014 + A1:2020 was pass.

- iii. **Human Factors and Usability Validation**

The usability engineering process was performed in accordance with the international standard “AAMI / ANSI / IEC 62366-1:2015 + A1:2020, *Medical Devices - Part 1: Application of Usability Engineering to Medical Devices*”. Usability impact assessments, comparing the Subject Device to the Predicate Device, were carried out to identify the hazard-related use scenarios affected by the changes. Summative evaluations of these scenarios were performed with five interventional oncologists in Europe; English was the language used for these evaluations, including for the user interface and instructions for use. Use of the device requires mandatory manufacturer training, which is identical worldwide. The Subject Device guides users through the same tasks in each workflow module. All participants completed the evaluated tasks, and no use errors were observed. The scope of the summative evaluations were strictly limited to the changes introduced for each respective version. The evaluations were not performed with 15 residents of the United States, and therefore, do not constitute complete human factors validation testing as described in the FDA guidance “*Applying Human Factors and Usability Engineering to Medical Devices – Guidance for Industry and Food and Drug Administration Staff (2016-02)*”.

The CAS-One IR Platform A was evaluated according to IEC 60601-1-6:2010 + A1:2013 + A2:2020 under the CB Scheme, in conjunction with IEC 62366-1:2015 + A1:2020. The usability engineering process was implemented in compliance with the applicable requirements, including risk assessment according to ISO 14971:2019. The evaluation fulfilled the usability requirements of IEC 60601-1-6 under the CB Scheme.

iv. Clinical Studies

Clinical testing was not required to demonstrate the safety and effectiveness of the Subject Device as compared to the Predicate. This conclusion is based upon a comparison of intended use, technological characteristics, and non-clinical performance data (software verification and validation testing (including internal test standards and segmentation validation), hardware verification and validation (including electrical safety and electromagnetic compatibility), and human factors and usability validation).

v. Cybersecurity

Cybersecurity was addressed in accordance with section 524B of the FD&C Act and FDA's guidance Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions. The documentation includes a security architecture description, threat modeling, a cybersecurity risk assessment, a Software Bill of Materials with a vulnerability assessment of third-party components, and a plan for postmarket monitoring and management of vulnerabilities. An independent third party performed security testing on the Subject Device configuration, CAS-One IR Software version 4.3 on Windows 11 IoT Enterprise LTSC. The testing included manual penetration testing of the application (thick client) and the platform, vulnerability scanning, port scanning, and CIS benchmark assessment of the operating system image. No critical or high-severity vulnerabilities were identified. Medium- and low-severity findings were identified, including the use of third-party software components with known vulnerabilities.

VIII. CONCLUSIONS

The Subject Device is substantially equivalent to the Predicate Device with regard to device performance and safety. This conclusion is based upon a comparison of the intended use, technological characteristics, and non-clinical performance testing. An impact assessment on usability, comparing the Subject Device to the Predicate Device, and summative usability testing of the changes were carried out and demonstrated that the Subject Device, as compared to the Predicate, is safe and effective for the intended users, uses, and use environments. Performance testing demonstrates that the Subject Device is safe and effective as compared to the Predicate. Therefore, it can be concluded that the Subject Device is substantially equivalent to the Predicate Device.