February 20, 2026

Cara Medical Ltd.
% Shimon Vaknin
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Re: K252500
Trade/Device Name: CARA System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, QIH
Dated: January 22, 2026
Received: January 22, 2026

Dear Shimon Vaknin:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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)*
K252500

Device Name
CARA System

Indications for Use *(Describe)*
The Cara System is intended for preplanning and guidance of medical interventions in an area known to contain or be adjacent to the cardiac conduction system, such as percutaneous or surgical procedures, for example, transcatheter aortic valve replacement (TAVR), as well as medical procedures where the physician desires to deliver therapy to the patient's cardiac conduction system or to a targeted location within it (CSP).
The Cara System uses computed tomography angiography (CTA)-based and user manually marked landmarks to identify the cardiac conduction axis and generate a three-dimensional (3D) map of the individual patient's cardiac conduction system. The system also overlays the anatomical location of the cardiac conduction system (generated by the Cara Metis Simulator using pre-procedure CT data) onto live fluoroscopic images.
The software utilizes AI/ML algorithms to provide OCR detection, automated segmentation of anatomical structures, and detection of catheters.
The CARA System is intended for use in adult patients (18 years of age and older).

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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**510(K) Summary - K252500**

**CARA Medical Ltd CARA System**

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**Date Prepared:** February 20, 2026

**Device Tradename:** CARA System

**Common or Usual Name:** Interventional Fluoroscopic X-Ray System

**Classification Name:** Image-intensified fluoroscopic x-ray system

**Regulation Number:** 21 CFR §892.1650

**Regulatory Class:** Class II

**Product Code: Primary -** OWB

**Secondary -** QIH

**Predicate Device**

The CARA System is substantially equivalent to the following predicate device:

- **Device Tradename:** Cydar EV (Series B), also referred to as Cydar EV Maps
- **510(k) Number:** K212442
- **Company:** Cydar Medical
- **Common or Usual Name:** Interventional Fluoroscopic X-Ray System
- **Classification Name:** Image-intensified fluoroscopic x-ray system
- **Regulation Number:** 21 CFR §892.1650
- **Regulatory Class:** Class II
- **Product Code:** OWB

## Device Description

The CARA System is a medical device comprising two integrated functions. The CARA System device components include the CARA Metis Simulator and the CARA Atlas Navigator. Both components provide diagnostic imaging software and hardware functions that identify the personalized anatomical location of the cardiac conduction system in relation to other heart anatomies based on a patient's computed tomographic angiography (CTA). The former is intended for preplanning (1) a medical intervention in an area known to contain or be adjacent to the cardiac conduction system or (2) a medical procedure(s) where the physician desires to deliver therapy to the patient's cardiac conduction system. The latter identifies the personalized anatomical location of the cardiac conduction system overlaid on real-time, intra-procedural, fluoroscopic imaging and provides guidance during interventional structural heart disease procedures in an area known to contain or be adjacent to the cardiac conduction system or where the physician desires to deliver therapy to the patient's cardiac conduction system.

**The CARA Metis Simulator** uses computed tomography angiography (CTA)-based landmarks to accurately identify the cardiac conduction axis and run a simulation generating the personalized three-dimensional (3D) map of the individual patient's cardiac conduction system.

This 3D map is then utilized by the clinical operator to plan any procedure to either target, as in direct pacing, or avoid as in structural heart disease interventions, the cardiac conduction system. As described below, this technology is based on methodical translational studies investigating the 3D location of the cardiac conduction system relative to cardiac structures visible by clinical imaging with initial assessment and validation in the clinical setting.

**The CARA Atlas Navigator** is designed to overlay the personalized anatomical location of the cardiac conduction system (generated by the Cara Metis Simulator using pre-procedure CT data) onto live fluoroscopic images. This functionality assists clinicians during fluoroscopy-guided interventional heart procedures.

The Cara Atlas Navigator consists of both software and hardware components:

1) **Fluoroscopy Splitter (F-Splitter)** – This device splits the live fluoroscopy image for integration with the CARA System.
2) **CARA Box** – A standard workstation that receives live fluoroscopy images from the Fluoroscopy Splitter and enhances them by adding anatomical landmarks. The CARA Box acts as the system's central processing unit, handling data analysis and image processing. It is equipped with user interface devices, such as a mouse and keyboard.
3) **CARA Monitor** – Displays the enhanced fluoroscopy images, including the analysis performed by the CARA Box. This monitor is typically located in the control room. The same output is also projected onto the main display in the operating room.

The CARA System utilizes a specific on-premises workflow to ensure data integrity and clinical accuracy. Prior to physician use, a certified CARA Clinical Expert (CCE) must be physically present on-site. The CCE logs into the CARA Box workstation to prepare the CARA Metis pre-planning process. This includes initiating the automated segmentation, verifying the anatomical output, annotating landmarks, and saving the results to the local storage.

The physician subsequently logs into the same workstation using distinct credentials to load, review, and confirm the pre-planned case. This workflow ensures that all generated outputs are professionally prepared and verified before clinical review.

The CARA System utilizes AI/ML algorithms to provide OCR (Optical Character Recognition), automated segmentations and device tracking:

- OCR detection - is used to automatically extract metadata from the live feed of the fluoroscopy machine (e.g., c-arm position, focal distance, etc.).
- Segmentations - the system utilizes deep learning models to automatically generate anatomical segmentations of the heart chambers and aorta.
- Device Detection - using a segmentation model the system detects the distal tips of specific interventional devices (e.g., Pigtail catheters, CS catheters, pacing leads) within the fluoroscopic image to support real-time tracking and present overlay.

AI-based segmentations are provided to assist the workflow but may contain inaccuracies. The AI output should not be used as the sole basis for clinical decision-making. Clinical oversight is mandatory.

### Intended Use / Indications for Use

The Cara System is intended for preplanning and guidance of medical interventions in an area known to contain or be adjacent to the cardiac conduction system, such as percutaneous or surgical procedures, for example, transcatheter aortic valve replacement (TAVR), as well as medical procedures where the physician desires to deliver therapy to the patient's cardiac conduction system or to a targeted location within it (CSP).

The Cara System uses computed tomography angiography (CTA)-based and user manually marked landmarks to identify the cardiac conduction axis and generate a three-dimensional (3D) map of the individual patient’s cardiac conduction system. The system also overlays the anatomical location of the cardiac conduction system (generated by the Cara Metis Simulator using pre-procedure CT data) onto live fluoroscopic images.

The software utilizes AI/ML algorithms to provide OCR detection, automated segmentation of anatomical structures, and detection of catheters.

The CARA System is intended for use in adult patients (18 years of age and older).

### Summary of Technological Characteristics

The CARA System comprises two integrated functions:

1. The Cara Metis Simulator is a Software as a Medical Device (SaMD).
2. The Cara Atlas Navigator is a Software preinstalled on a standard workstation that receives live fluoroscopy images via the Splitter. The system is supplied with an isolation transformer.

The CARA system does not contact the patient, nor does it control any life sustaining device. The use of the CARA system in pre-operative planning, intra-operative mapping and postoperative follow-up is dependent on the interpretation of trained clinical specialists.

CARA MEDICAL

## Predicate Device Comparison

The CARA System demonstrates substantial equivalence to the predicate device through a similar fundamental technological approach, regulatory classification, and comparable risk profile, with differences limited to anatomical specialization that does not affect safety or effectiveness.

A table comparing the key features of the subject and predicate device is provided below.

## Substantial Equivalence Comparison Table

| Feature | Cara Medical System (subject device) | Cydar EV (Series B) and Cydar EV Maps (predicate device) | Comments |
|---|---|---|---|
| **510(k) Number** | K252500 | K212442 | |
| **Regulation** | 21 CFR 892.1650 | 21 CFR 892.1650 | Identical |
| **Regulatory Class** | Class II | Class II | Identical |
| **Product Code** | OWB | OWB | Identical |
| **Intended Use/ Indications for Use** | The Cara System is intended for preplanning and guidance of medical interventions in an area known to contain or be adjacent to the cardiac conduction system, such as percutaneous or surgical procedures, for example, transcatheter aortic valve replacement (TAVR), as well as medical procedures where the physician desires to deliver therapy to the patient's cardiac conduction system or to a targeted location within it (CSP).<br><br>The Cara System uses computed tomography angiography (CTA)-based and user manually marked landmarks to identify the cardiac conduction axis and generate a three-dimensional (3D) map of the individual patient's cardiac conduction system. The system also overlays the anatomical location of the cardiac conduction system (generated by the Cara Metis Simulator using pre-procedure CT data) onto live fluoroscopic images. | Cydar EV provides tools to:<br>• Import and visualise CT data<br>• Segment and annotate vascular anatomy from CT data<br>• Place and edit virtual guidewires and measure lengths on them<br>• Make measurements of anatomical structures on planar sections of the CT data<br>• Produce an operative plan from measurements and segmentation of preoperative vessel anatomy<br>• Overlay planning information such as preoperative vessel anatomy onto live fluoroscopic images, aligned<br>• based on the position of anatomical features present in both<br>• Non-rigidly transform the visualisation of anatomy when intra-operative vessel deformation is observed<br>• Post-operatively review data relating to procedures where the system was used<br>Cydar EV is intended to assist fluoroscopic X-ray guided endovascular procedures in the chest, abdomen, and | Substantially equivalent. Both devices utilize the same fundamental technology (CT-to-fluoroscopy overlay). The anatomical focus difference (cardiac conduction system vs. general vasculature) represents a subset application that does not introduce new safety or effectiveness concerns, as both rely on identical image registration within the vascular system and overlay principles. |

| Feature | Cara Medical System (subject device) | Cydar EV (Series B) and Cydar EV Maps (predicate device) | Comments |
|---|---|---|---|
| | The software utilizes AI/ML algorithms to provide OCR detection, automated segmentation of anatomical structures, and detection of catheters.<br><br>The CARA System is intended for use in adult patients (18 years of age and older). | pelvis by presenting the operative plan in the context of intraoperative fluoroscopy. Cydar EV is intended to be used for patients undergoing a fluoroscopic X-ray guided endovascular surgery in the chest abdomen and pelvis, and who have had a pre-operative CT-scan.<br>The performance of the Cydar EV software in the presence of immature vertebral anatomy is unknown. The Instructions for Use explicitly state this uncertainty and that the software is therefore not recommended for use in patients under the age of 18.<br><br>IMPORTANT: Pre-Operative Maps show static anatomy derived from the pre-operative CT. Real-time anatomy moves with the cardiorespiratory cycle; progressive disease may cause the anatomy to change over time; and stiff wires, stents or other surgical instruments, may straighten and displace blood vessels from the preoperative position<br>It is therefore mandatory to check the real-time anatomy with a suitable imaging technique, such as contrast angiography, before deploying any invasive medical device. | |
| **User Population** | Patients above the age of 18 | Patients above the age of 18 | Identical |
| **Environment of Use** | Operating room, office (during planning) | Operating room, office (during planning) | Identical |
| **Major Components** | Standard workstation (Cara Box)<br>Standard Fluoroscopy splitter<br>Standard Monitor | Standard workstation<br>Standard Fluoroscopy splitter | Similar, both use standard hardware; the addition of a standard commercially available monitor for the Cara Medical System does not raise new questions of safety or effectiveness. |
| **Interface to Image Sources** | Local DICOM files | Local DICOM files or distant PACS server. | Similar, both systems accept DICOM files and provide comparable image source integration. |
| **Import of Patient Data** | Via DICOM imaging files | Via DICOM or PACS imaging files | Similar, both systems import patient data from |

| Feature | Cara Medical System (subject device) | Cydar EV (Series B) and Cydar EV Maps (predicate device) | Comments |
|---|---|---|---|
| | | | DICOM or PACS files with no functional differences impacting safety or effectiveness. |
| **List Image Functionality** | Segment and annotate cardio-vascular anatomy from CT data | Segment and annotate vascular anatomy from CT data | Same |
| **Anatomical Region** | Cardiac conduction system | General vasculature | Similar; while these devices target different regions, they are both designed to segment and annotate vascular anatomy. |
| **Image Processing** | Place and edit anatomical landmarks and Make measurements of anatomical structures on planar sections of the CT data. | Place and edit virtual guidewires and measure lengths on them Make measurements of anatomical structures on planar sections of the CT data. | Same |
| **Image and 3D Display** | Overlay planning information onto live fluoroscopic images, aligned based on the position of anatomical features and/or catheters present in both. | Overlay planning information such as preoperative vessel anatomy onto live fluoroscopic images, aligned based on the position of anatomical features present in both. | Similar, both systems overlay planning information onto fluoroscopic images based on anatomical alignment, with no differences affecting the intended purpose. |
| **DICOM Support** | Import DICOM files | Import DICOM files | Identical |
| **Preoperational Planning** | Import and visualize CT data; Segment and annotate cardio-vascular anatomy from CT data; Place and edit anatomical landmarks; Make measurements of anatomical structures on planar sections of the CT data; Visualize the segmented cardio-vascular anatomy. | Import and visualize CT data; Segment and annotate vascular anatomy from CT data; Place and edit virtual guidewires and measure lengths on them; Make measurements of anatomical structures on planar sections of the CT data; Visualize the segmented vascular anatomy, annotations +/- measurements together (the 'Operative Plan') | Similar, both systems support CT-based preoperative planning with annotation and measurement tools. Differences reflect clinical focus but do not alter core functionality or intended use. |
| **Patient Contact** | No | No | Identical |
| **Human Intervention for Interpretation of Images** | Yes<br>The information and measurements displayed, exported or printed are validated and interpreted by Physicians. | Yes<br>The information and measurements displayed, exported or printed are validated and interpreted by Physicians. | Identical |
| **Functionality** | Generates a detailed 3D model of the patient's cardiac conduction system tailored to planned procedure.<br><br>Overlays the personalized anatomical location of the | Intra-operative (Fusion imaging functions): Overlay planning information such as preoperative vessel anatomy onto live fluoroscopic images, aligned based on the position of anatomical features present in both; Non-rigidly transform | Similar, both systems overlay anatomical models onto live fluoroscopy based on shared landmarks. Differences reflect clinical application but maintain the same core imaging guidance function. |

| Feature | Cara Medical System (subject device) | Cydar EV (Series B) and Cydar EV Maps (predicate device) | Comments |
|---|---|---|---|
| | cardiac conduction system onto live fluoroscopic images. | the visualization of anatomy when intra-operative vessel deformation is observed. Post-operative (Review functions): Postoperatively review data relating to procedures where the system was used. | |
| **AI / ML Segmentation and Image Processing** | AI/ML algorithms are used for OCR metadata extraction, automated CT-based anatomical segmentation and fluoroscopic device detection. Outputs require physician review prior to clinical use. | Utilizes deep learning algorithms for CT-based vascular segmentation and automated volume analysis. Fluoroscopic image registration and overlay are performed using image processing and tracking methods as described in the User Manual. | Both devices incorporate automated CT-based segmentation and image registration technologies to generate 3D anatomical models and support fluoroscopic overlay. Differences relate to anatomical target and algorithm implementation and do not alter the fundamental technological principles. |

## Intended Use Discussion

The Cara Medical System and the predicate device, Cydar EV (Series B) and Cydar EV Maps (K212442), share a substantially equivalent intended use. Both devices are designed to provide imaging guidance for medical procedures by overlaying pre-procedural anatomical planning information onto real-time, intra-procedural fluoroscopic images.

Specifically, the Cara Medical System's intended use is to assist healthcare practitioners in the preplanning and guidance of medical interventions in an area known to contain or be adjacent to the cardiac conduction system, such as percutaneous or surgical procedures, for example, transcatheter aortic valve replacement (TAVR), as well as medical procedures where the physician desires to deliver therapy to the patient's cardiac conduction system or to a targeted location within it (CSP).

The predicate device, Cydar EV, is intended to assist fluoroscopic X-ray guided endovascular procedures in the chest, abdomen, and pelvis by presenting an operative plan in the context of intraoperative fluoroscopy. Its functionalities include importing and visualizing CT data, segmenting and annotating vascular anatomy, placing virtual guidewires, making measurements, producing operative plans, overlaying planning information onto live fluoroscopic images, and non-rigidly transforming the visualization of anatomy when intra-operative vessel deformation is observed.

While the Cara Medical System focuses specifically on the cardiac conduction system and related structural heart procedures, and the Cydar EV focuses on general vascular anatomy in endovascular procedures, the fundamental purpose of both devices remains the same: to utilize pre-procedural CT data to create an anatomical roadmap that is then overlaid onto live fluoroscopic images to guide interventional procedures. The anatomical focus of the Cara Medical System represents a subset

application within the broader scope of image-guided interventions, and this anatomical specialization does not introduce new safety or effectiveness concerns. Both systems operate on the identical principle of CT-to-fluoroscopy overlay and image registration. Both devices are intended for use by healthcare practitioners in similar environments (operating rooms, offices for planning) and for similar patient populations (patients above 18).

Therefore, despite the difference in the specific anatomical regions addressed, the overall intended use and clinical application of assisting fluoroscopic-guided interventions through advanced imaging overlay are substantially equivalent.

**Technological Discussion**

The CARA System and the predicate device (Cydar EV) share the same fundamental technological approach regarding image registration, DICOM processing, and fluoroscopic overlay. Both systems operate on the principle of registering pre-operative Computed Tomography (CT) data with real-time intra-procedural fluoroscopic images to provide 3D anatomical guidance.

**Image Data Handling** - Both systems import patient data via DICOM imaging files. The Cydar EV also supports PACS integration, which is a minor difference in data access method that does not affect the core image processing or output. Both devices perform similar image functionalities, including segmenting and annotating anatomical structures from CT data. While the Cara System focuses on cardio-vascular anatomy and the predicate on vascular anatomy, the underlying segmentation and annotation algorithms and principles are similar.

The predicate device utilizes deep learning algorithms for CT-based vascular segmentation and automated volume analysis, as described in its User Manual. The subject device utilizes AI/ML-based deep learning algorithms to perform automated CT-based segmentation of cardiac chambers and aorta, as well as anatomical landmark-based modeling of the cardiac conduction system.

Although the anatomical targets differ (vascular anatomy versus cardiac conduction system), both systems generate CT-derived 3D anatomical models through similar automated image processing techniques. In both devices, segmentation outputs are subject to clinician review and confirmation prior to procedural reliance.

**Planning and Measurement Tools** - Both systems offer pre-operational planning capabilities that involve visualizing CT data, segmenting and annotating anatomy, and performing measurements. The Cara System allows for placing and editing anatomical landmarks and making measurements of anatomical structures on planar sections of the CT data, while the Cydar EV allows for placing and editing virtual guidewires and making similar measurements. These differences are reflective of their specific clinical applications (cardiac conduction vs. general vascular guidance) but represent comparable image processing and planning tools.

**Intra-Procedural Guidance** - The most critical technological similarity lies in their intra-operative capabilities. Both devices overlay planning information (personalized anatomical models for Cara, preoperative vessel anatomy for Cydar EV) onto live fluoroscopic images. This alignment is based on

the position of anatomical features or catheters present in both imaging modalities. The Cara System's ability to overlay the personalized anatomical location of the cardiac conduction system aligns directly with the Cydar EV's function to overlay planning information, such as preoperative vessel anatomy onto live fluoroscopic images.

The predicate device employs image registration and tracking methods, as described in its User Manual, to align CT-derived vascular models with live fluoroscopy. The subject device performs CT-to-fluoroscopy registration using anatomical landmarks and incorporates AI-based device detection and OCR metadata extraction to assist in overlay initialization and refinement.

Although the subject device incorporates additional automated workflow-support features, the fundamental technological characteristic in both systems is CT-derived model registration and fluoroscopic overlay visualization under user control.

**Hardware and Software Platform** - Both devices utilize standard workstation hardware and interface with standard fluoroscopy splitters and monitors. The software architecture for both is based on processing DICOM inputs and generating graphical overlays.

**Patient Contact and Human Intervention** - Neither device has direct patient contact. Both require human intervention for interpretation of images, with physicians validating and interpreting the displayed information and measurements, ensuring clinical oversight is maintained.

**Artificial Intelligence and Automated Image Processing -** The CARA System and the predicate device incorporate automated CT-based image processing to generate patient-specific three-dimensional anatomical models and to support CT-to-fluoroscopy registration and overlay during interventional procedures.

The predicate device utilizes deep learning algorithms for CT-based vascular segmentation and automated volume analysis and employs image registration and tracking methods to align CT-derived vascular models with live fluoroscopy. The subject device utilizes AI/ML-based algorithms for CT-based cardiac anatomical segmentation, conduction system modeling, OCR-based metadata extraction, and fluoroscopic device detection to assist in overlay initialization and refinement.

In both systems, automated outputs are intended to support procedural planning and intra-procedural guidance and are subject to clinician review and confirmation.

The technological differences relate to anatomical specialization (cardiac conduction system versus vascular anatomy) and specific algorithm implementation. However, both devices operate within the same fundamental technological framework of automated CT segmentation, model generation, and fluoroscopic overlay guidance under physician control.

Accordingly, these differences do not alter the intended use, do not change the fundamental mode of operation, and do not raise new questions of safety or effectiveness, supporting substantial equivalence under 21 CFR 807.92(a)(6).

## Performance Data

Comprehensive non-clinical, AI/ML validation, and retrospective clinical performance testing were conducted to demonstrate substantial equivalence in accordance with 21 CFR 807.92(b)(1) and (b)(2).

## 1. Non-Clinical Performance Data

The device software was verified and validated in accordance with IEC 62304, and cybersecurity controls were validated against NIST SP 800-53 and FDA guidance to confirm the air-gapped architecture. Electrical safety and EMC testing confirmed compliance with IEC 60601-1 and IEC 60601-1-2.

In addition, system-level bench testing was performed to validate CT-to-fluoroscopy registration accuracy, system latency, and image fidelity.

CT-to-fluoroscopy registration testing validated geometric alignment between the CT-derived model and live fluoroscopy using landmark-based comparison against ground truth in phantom. The system achieved a mean registration error of ≤ 2.0 mm and a maximum error of ≤ 3.0 mm, meeting predefined thresholds within clinically acceptable limits for fluoroscopic overlay systems.

System latency was evaluated using frame-based timing analysis with calculation of the 95% upper confidence bound. The system demonstrated latency of ≤ 133 ms (95% upper bound), supporting real-time synchronization during intra-procedural guidance.

Image fidelity testing assessed preservation of image quality during processing using Peak Signal-to-Noise Ratio (PSNR) and Structural Similarity Index (SSIM). The system maintained PSNR ≥ 35 dB and SSIM ≥ 0.95, confirming preservation of diagnostic image detail.

## 2. AI/ML Algorithm Performance

The CARA System incorporates AI/ML algorithms for optical character recognition (OCR), CT-based anatomical segmentation, and fluoroscopic device detection.

Algorithms were trained using retrospective, multi-site clinical datasets. Data augmentation techniques (e.g., rotation, scaling, and noise injection) were applied to support generalizability. Training and test datasets were independent.

Reference annotations used for validation were generated by trained technologists and adjudicated by a U.S. Board-Certified Interventional Cardiologist.

### AI/ML Performance Summary

| Feature | Intended Function | Test Dataset (n) | Ground Truth Method | Primary Metric | Acceptance Criteria | Results |
|---|---|---|---|---|---|---|
| **Optical Character Recognition (OCR)** | Extraction of fluoroscopic metadata | 61 fluoroscopic images | Manual verification of extracted parameters | Error rate | 0 errors (≤5% upper 95% CI bound) | 0 failures observed |
| **Anatomical Segmentation (Cardiac Chambers)** | CT-based 3D anatomical model generation | 50 retrospective CT scans | Manual segmentation by trained technologists with physician adjudication | Dice Similarity Coefficient; Average Surface Distance | DSC ≥ 0.85; ASD ≤ 1.5 mm | All evaluated structures met criteria |
| **Aortic Segmentation** | Fluoroscopic aortic segmentation for registration | 480 fluoroscopic images | Manual contour annotation with physician adjudication | Dice Similarity Coefficient | DSC ≥ 0.85 | Mean DSC = 0.962 |
| **Catheter & Lead Detection** | Distal tip localization | 2,139 fluoroscopic images | Manual distal tip annotation | Median distal tip | ≤ 0.9 mm | All evaluated catheter |

| | | | | | | |
|---|---|---|---|---|---|---|
| | during fluoroscopy | | with physician adjudication | localization error | | types met criteria |

### 3. Clinical Performance Data

A retrospective clinical study was conducted on 403 patients to evaluate the device's utility in visualizing the conduction system during interventional procedures.

- TAVR Cohort (n=228): Evaluated the association between the CARA-visualized Conduction System Axis (CSA) and post-procedural outcomes. In the retrospective dataset, implantation above the CARA-visualized CSA was observed to be associated with different rates of Permanent Pacemaker Implantation (11.2% vs. 33.9%).
- CSP Cohort (n=175): Evaluated pacing effectiveness relative to the CARA-visualized Left Bundle Branch (LBBP). Pacing at sites identified by CARA as the LBBP was associated with improved cardiac function (Mean LVEF improvement +11.2%) compared to non-specific septal pacing (+0.3%).

No device-related adverse events were identified in the retrospective evaluation.

## Conclusions

Based on the intended use, technological characteristics, and performance data presented in this submission, the CARA System has been demonstrated to be as safe and effective as the predicate device, Cydar EV (K212442). The subject and predicate devices share a similar intended use, operate under the same regulatory classification, and utilize comparable CT-based anatomical modeling and fluoroscopic overlay principles.

Any technological differences, including anatomical specialization and algorithm implementation, do not alter the fundamental mode of operation and do not raise new questions of safety or effectiveness.

Accordingly, the CARA System is substantially equivalent to the Cydar EV device in accordance with 21 CFR 807.92.