December 3, 2021

Cydar Ltd.
% Vanisha Mistry
Head of Compliance
Bulbeck Mill, Mill Lane
Barrington, Cambs CB22 7QY
UNITED KINGDOM

Re: K212442
Trade/Device Name: Cydar EV Series B, Cydar EV Maps
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: November 3, 2021
Received: November 5, 2021

Dear Vanisha Mistry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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 located 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212442

Device Name
Cydar EV Series B, Cydar EV Maps

Indications for Use *(Describe)*
Cydar EV provides tools to:

- Import and visualise 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
- Produce an operative plan from measurements and segmentation of preoperative vessel anatomy
- 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 the visualisation of anatomy when intra-operative vessel deformation is observed
- Post-operatively review data relating to procedures where the system was used

Cydar EV is intended to assist fluoroscopic X-ray guided endovascular procedures in the chest, abdomen, and 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.

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.

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 pre-operative position

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.

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.

Cydar Medical

Cydar Ltd 510(k) Submission: Cydar EV Series B

Section 5: 510(k) Summary

Wed Nov 3 (git: 2a6272a)

Contents

S05.1 Section 5: 510(k) Summary

S05.1.1 Submitter Details

Business Name	Cydar Ltd
Address	Bulbeck Mill Barrington Cambridgeshire CB22 7QY UK

Contact person:

Name	Rob Hague
Position	CTO
Phone number	+44 1223 778 020
Email	rob.hague@cydar.co.uk

US Agent:

Contact Name	Michael van der Woude
Business Name	Emergo Global Representation LLC
Address	2500 Bee Cave Road Bldg 1, Suite 300 Austin, TX 78746 United States
Phone	512 327-9997
Fax	512 327-9998
Email	USAgent@UL.com

This summary was prepared on 2021-11-03.

S05.1.2 Device Name

The device is know as *Cydar EV*. It is an an evolution of a previous device of the same name, which is the subject of 510(k) *K160088*. To distinguish the two devices, the older device is referred to as *Cydar EV Series A*, and the device that is the subject of this application *Cydar EV Series B*. Unless otherwise stated, *Cydar EV* in this application refers to the subject device, *Cydar EV Series B*.

Both devices are referred to as *Cydar EV* or *Cydar EV Maps* in all literature supplied to the user, with a version number to distinguish a specific release of the software. At the time *Cydar EV Series B* is placed on the market, the next version number will be assigned to the first release of that device.

Type of 510(k) Submission	Traditional
Trade or Proprietary Name	Cydar EV Also referred to as Cydar EV Series B, Cydar EV Maps
Common or Usual Name	Interventional Fluoroscopic X-Ray System
Regulation Number	21 CFR 892.1650
Product Code	OWB, Interventional Fluoroscopic X-Ray System
Class of Device	Class II
Panel	Radiology
Multiple Devices	None.

S05.1.3 Predicate Device Identification

All aspects of Cydar EV's functionality are substantially equivalent to one or both legally marketed predicate devices listed below.

Device	Manufacturer	510(k)	Scope
Cydar EV (primary predicate)	Cydar Ltd	K160088	CT import, intra-operative overlay, post-operative review
Endosize	Therenva SAS	K141475	Measurements and segmentation on CT scans

S05.1.4 Device Description

Cydar EV is a Software-as-a-Service product and consists only of the software running on Cydar's cloud servers. Cydar EV enables expert clinical users to build an operative plan, called a Pre-operative Map, which consists of 3D blood vessel anatomy from the patient's CT scan, measurements, and other annotations deemed relevant by the clinical user. During surgery, Cydar EV's fusion imaging superimposes the Pre-operative Map on a duplicated display of the X-ray fluoroscopy. The clinical users can interact and non-rigidly transform a copy of the Map, called the Adjusted Map, when they see that the real-time anatomy has deformed. After surgery, clinical users can review data about the case via the web interface.

No specific accessories are required for the use of Cydar EV. The software is provided as a service and accessed via standard web browser. For intra-operative fusion imaging use, the browser is run on a client PC device called the Cydar Appliance. The Cydar Appliance is an off-the-shelf PC with an off-the-shelf video frame grabber and is not in itself a medical device nor considered in the scope of this 510(k) submission. The Windows image on the PC (ie Cydar Appliance) is controlled by Cydar and not configurable by the end-user. The Cydar Appliance may display its output on one or more external monitors via standard video connections e.g DVI or HDMI (in addition to any built-in display). A particular installation of the PC (ie Cydar Appliance) may provide a touchscreen and/ or peripheral devices such as mice, trackpads, keyboards, and handheld remote control to operate the user interface of the Cydar EV service. The software implementing the upload of CT scans in DICOM format ('Cydar Gateway ') is a medical image communications device and is therefore also not considered in the scope of this 510(k) submission.

S05.1.5 Statement of Intended Use

Cydar EV provides tools to:

- Import and visualise 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
- Produce an operative plan from measurements and segmentation of preoperative vessel anatomy
- 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 the visualisation of anatomy when intra-operative vessel deformation is observed
- Post-operatively review data relating to procedures where the system was used

S05.1.5.1 Indications for Use

Cydar EV is intended to assist fluoroscopic X-ray guided endovascular procedures in the chest, abdomen, and 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.

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.

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 pre-operative position

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.

S05.1.5.2 Differences from Predicate Device

The Indications for Use for Cydar EV Series B are similar to those for Cydar EV Series A (identified as the primary predicate device), with the addition of measurement functionality similar to that indicated for Endosize. Where there are differences, the clinical data demonstrates that this does not impact safety or performance. More detail on this correspondence is provided in the next section.

S05.1.6 Predicate Device Comparison

The following table compares the Cydar EV Series B to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Conclusion: No difference in intended surgical interventions between these devices. However the intended targeted anatomy is clarified in Cydar EV Series B. See section (add Section references)in this summary.

Assessment Criteria	**Cydar EV Series B** **Cydar Medical Ltd** **Device under assessment**	**Cydar EV Series A** **Cydar Medical Ltd** **Primary Equivalent Device** **K160088**	**EndoSize** **Therenva** **Secondary Equivalent Device** **K141475**	**Identified differences or conclusion of no difference**
1. Technical Characteristics				

Assessment Criteria	**Cydar EV Series B** **Cydar Medical Ltd** **Device under assessment**	**Cydar EV Series A** **Cydar Medical Ltd** **Primary Equivalent Device** **K160088**	**EndoSize** **Therenva** **Secondary Equivalent Device** **K141475**	**Identified differences or conclusion of no difference**
Intended Use	Cydar EV provides tools to: • Import and visualise 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 • Produce an operative plan from measurements and segmentation of preoperative vessel anatomy • 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 the visualisation of anatomy when intra-operative vessel deformation is observed • Post-operatively review data relating to procedures where the system was used	Cydar EV is intended to display combined live 2D X-ray fluoroscopy and 3D anatomy for image guidance during surgery. Features of the device include: Import and visualise CT scan data. Segment and annotate vascular anatomy from CT data. Produce an operative plan Overlay planning information such as preoperative vessel anatomy onto live fluoroscopic images, aligned based on the position of anatomical features present in the fluoroscopic images. Non-rigidly transform the visualisation of anatomy when intra-operative vessel deformation is observed.	EndoSize is a software solution that is intended to provide Physicians and Clinical Specialists with additional information to assist them in reading and interpreting DICOM CT scan images of structures of the heart and vessels. EndoSize enables the user to visualize and measure (diameters, lengths, volumes, angles) structures of the heart and vessels.	Conclusion: Cydar EV Series B is similar intended use to the primary predicate device differing only in additional features; placement and editing virtual guidewires, measurement of lengths and measurement of anatomical structures on planar sections of CT data is similar to the secondary predicate device. Measurement accuracy verification testing and summative user study is performed as part of the design and development process

Assessment Criteria	**Cydar EV Series B** **Cydar Medical Ltd** **Device under assessment**	**Cydar EV Series A** **Cydar Medical Ltd** **Primary Equivalent Device** **K160088**	**EndoSize** **Therenva** **Secondary Equivalent Device** **K141475**	**Identified differences or conclusion of no difference**
Indications for use	Cydar EV is intended to assist fluoroscopic X-ray guided endovascular procedures in the chest, abdomen, and 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. 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. **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 pre-operative position **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.**	Cydar EV provides image guidance by overlaying preoperative 3D vessel anatomy from a previously acquired contrast-enhanced, diagnostic CT scan onto live X-ray fluoroscopy images in order to assist in the positioning of guidewires, catheters and other endovascular devices. Cydar EV is intended to assist X-ray fluoroscopy-guided endovascular procedures in the lower thorax, abdomen and pelvis. Suitable procedures include endovascular aortic aneurysm repair, angioplasty, stenting and embolization in the common iliac, proximal external iliac and proximal internal iliac arteries and corresponding veins. Cydar EV is not intended for use in X-ray guided procedures in the liver, kidneys or pelvic organs.	Therenva Endosize enables visualization and measurement of structures of the heart and vessels for pre-operational planning and sizing for cardiovascular interventions and surgery General functionalities are provided such as: • Segmentation of cardiovascular structures • Automatic and manual centreline detection • Visualisation of CT scan images in every planes, 2D review, 3D reconstruction, Volume Rendering, MPR, Stretched CMPR • Measurement and annotation tools • Reporting tools	Conclusion: Changes in wording clarifying target anatomy between Cydar EV Series B and primary predicate are detailed in the section beneath this table. Other differences these statements includes clarifications for the following which are present and equivalent in both devices: Adjustment in anatomy to have the option to non-rigidly transform the visualisation of the anatomy in the Map Statement clarifies device has not been tested on under 18's immature vertebral anatomy. Cydar EV series B allows preoperative and intraoperative imaging, Endosize allows preoperative imaging only.Other differences between Cydar EV Series B and primary predicate are as detailed in the section beneath this table, the additional features: placement and editing virtual guidewires, measurement of lengths and measurement of anatomical structures on planar sections of CT data. Measurement accuracy verification testing and summative user study is performed as part of the design and development process.

Assessment Criteria	**Cydar EV Series B** **Cydar Medical Ltd** **Device under assessment**	**Cydar EV Series A** **Cydar Medical Ltd** **Primary Equivalent Device** **K160088**	**EndoSize** **Therenva** **Secondary Equivalent Device** **K141475**	**Identified differences or conclusion of no difference**
Classification Product code / regulation	OWB; Interventional Fluoroscopic X-Ray System: Regulation: 892.1660	OWB; Interventional Fluoroscopic X-Ray System Regulation Regulation: 892.1660	LLZ ; System image processing radiology Regulation: 892.2050	OWB sufficiently covers the intended use of Cydar EV.
Construction	Software product	Software product	Software Product	No difference
Performance	**Preoperative planning:** Import and visualise 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; Visualise the segmented vascular anatomy, annotations +/- measurements together (the 'Operative Plan') **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 the visualisation of anatomy when intra-operative vessel deformation is observed **Post-operative (Review functions):** Post-operatively review data relating to procedures where the system was used	**Preoperative planning:** Import and visualise CT data; Segment and annotate vascular anatomy from CT data; Visualise the segmented vascular anatomy, annotations +/- measurements together (the 'Operative Plan') **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 the visualisation of anatomy when intra-operative vessel deformation is observed **Post-operative (Review functions):** Post-operatively review data relating to procedures where the system was used	**Preoperative planning:** Visualisation, annotations and measurement performed by clinicians intended to provide referring physicians with clinically relevant information for diagnosis, surgery, and treatment planning.	Conclusion: Difference between Cydar EV Series B and primary predicate are features; place and edit virtual guidewires and measure lengths on them and make measurements of anatomical structures on planar sections of the CT data EndoSize is indicated for preoperative planning only Measurement accuracy verification testing and summative user study is performed as part of the design and development process

Assessment Criteria	**Cydar EV Series B** **Cydar Medical Ltd** **Device under assessment**	**Cydar EV Series A** **Cydar Medical Ltd** **Primary Equivalent Device** **K160088**	**EndoSize** **Therenva** **Secondary Equivalent Device** **K141475**	**Identified differences or conclusion of no difference**
Design	Cydar EV Series B device is a software only medical device that runs on a standard computer that meets the minimum requirements. It can use local DICOM files or distant PACS server. The device does not contact the patient, nor does it control any life sustaining devices. The information and measurements displayed, exported or printed are validated and interpreted by Physicians. EV Maps complies with the DICOM voluntary standards (ACR/NEMA Digital Imaging and Communication in Medicine).	Cydar EV is a software only medical device that runs on a standard computer that meets the minimum requirements. It can use local DICOM files or distant PACS server. The device does not contact the patient, nor does it control any life sustaining devices. The information and measurements displayed, exported or printed are validated and interpreted by Physicians. EV complies with the DICOM voluntary standards (ACR/NEMA Digital Imaging and Communication in Medicine).	EndoSize is a software-only device that runs on a standard computer that meets the minimum requirements. It can use local DICOM files or distant PACS server. The device does not contact the patient, nor does it control any life sustaining devices. The information and measurements displayed, exported or printed are validated and interpreted by Physicians. EndoSize complies with the DICOM voluntary standards (ACR/NEMA Digital Imaging and Communication in Medicine)	Conclusion: No difference to design between Cydar EV Series B and primary predicate, this includes no difference to algorithim or development process.
2. Clinical Characteristics				
Same clinical condition or purpose, including similar severity and stage of disease	Cydar EV is intended only 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. The clinical procedures indicated for the Cydar EV devices are the same. For these procedures a clinical specialist will determine the stage of disease is advanced and requires intervention. Cydar EV devices are used for guidance during the procedure.	Cydar EV (Series A) is intended to assist fluoroscopy-guided endovascular procedures in the lower thorax, abdomen and pelvis. Suitable procedures include (but are not limited to) endovascular aortic aneurysm repair, (AAA and mid-distal TAA), stenting, and embolisation in the common iliac, proximal external iliac and proximal internal iliac arteries and their corresponding veins. Cydar EV (Series A) is not intended for use in X-ray guided procedures in the liver, kidneys or pelvis organs.	Intended for patients who require cardiovascular interventions, EVAR, TEVAR, TAVI and Peripheral	
Anatomical Site	Device is used indicated for fluoroscopic X-ray guided endovascular procedures in the chest, abdomen, and pelvis	Device is used indicated for fluoroscopic X-ray guided endovascular procedures in the lower thorax, abdomen, and pelvis	Device is used indicated for heart and vessels	No significant difference. The anatomy is clarified in this document (add Section references).

Assessment Criteria	**Cydar EV Series B Cydar Medical Ltd Device under assessment**	**Cydar EV Series A Cydar Medical Ltd Primary Equivalent Device K160088**	**EndoSize Therenva Secondary Equivalent Device K141475**	**Identified differences or conclusion of no difference**
User Profile	The target clinical users for the Cydar EV Series B device are experienced medical practitioners specialising in endovascular surgery (such as vascular surgeons and interventional radiologists) radiographers, and specialist nurses. Other users of the planning functions may include medical device company representatives and product specialists.	The target clinical users for the Cydar EV Series B device are experienced medical practitioners specialising in endovascular surgery (such as vascular surgeons and interventional radiologists) radiographers, and specialist nurses.	Physicians and clinical specialists, users involved in preoperative planning	No difference in targeted users
Patient Contact	No patient contact	No patient contact	No patient contact	No difference
Clinical Environment	Operating room, office (during planning)	Operating room, office (during procedure planning)	Office (during procedure planning)	Conclusion: No significant difference. Cydar EV Series B and secondary predicate differ slightly in intended clinical environment as the predicate is not intended for intra-operative use.
3. Non-clinical performance data				
Standards	IEC 62304 IEC 62366 ISO 14971	IEC 62304 IEC 62366 ISO 14971	IEC 62304 ISO 14971	Equivalent standards applied
NEMA PS 3.1-3.20 DICOM	Applied	Applied	Applied	Conclusion: No difference

The changes in wording of the Indications for Use statement from Cydar EV Series A (predicate) to B (device under review) are for the purposes of simplicity and clarity and do not convey any change in the clinical use, accuracy, reliability, safety, or performance. The change in wording from ‘lower thorax’ to ‘chest’ is for consistency in conveying the intended clinical use, as opposed to mode of action. The update in wording to remove statements pertaining to use in solid organs is clarified by the restriction to use in endovascular surgery. Cydar EV Series B described in this 510(k) has similar intended use as Cydar EV Series A, differing only in the additional features; Placement and editing virtual guidewires and measurement of lengths and measurement of anatomical structures on planar sections of CT data. The second predicate device; Endosize does include these features and is intended for preoperative planning only.

The subject device has undergone verification and validation activities to ensuring function and performance is as well as the predicate device and the additional features provide accurate and reliable outputs. The results support that the subject is substantially equivalent to the predicate devices.

S05.1.7 Technological Characteristics

Cydar EV, the subject device, is a software medical device, it does not contact the patient, nor does it control any life sustaining device. The use of this software in pre-operative planning, intra-operative mapping and post-operative follow-up is dependant on the interpretation of trained clinical specialists.

S05.1.8 Performance Data

Software verification and validation were conducted to establish the performance, functionality and reliability characteristics of this device, with particular focus on the modified features. The device has passed all of the tests beased on pre-determined Pass/Fail criteria.

S05.1.9 Benefit- Risk Conclusion

The device under review is substantially equivalent in the areas of general function, application, technical characteristics and use. The intended use differs only in differing only in additional features; Placement and editing virtual guidewires and measurement of lengths and measurement of anatomical structures on planar sections of CT data. The device does not introduce a fundamentally new scientific technology and has undergone bench testing to verify accuracy and user validation. Therefore, we conclude the benefits of Cydar EV when used according to the indications for use outweighs risks identified.