DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Cydar Ltd.
% Mr. Richard Vincins
Vice President, QA/RA
Emergo Global Consulting, LLC
816 Congress Avenue, Suite 1400
AUSTIN TX 78701

July 7, 2016

Re: K160088
Trade/Device Name: Cydar EV
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB
Dated: May 24, 2016
Received: June 1, 2016

Dear Mr. Vincins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160088

Device Name
Cydar EV

Indications for Use *(Describe)*
Cydar EV provides image guidance by overlaying preoperative 3D vessel anatomy, from a previously acquired contrast-enhanced, diagnostic CT scan, onto live fluoroscopic images in order to assist in the positioning of guidewires, catheters and other endovascular devices.

Cydar EV 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), 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 the X-ray guided procedures in the liver, kidneys or pelvic organs.

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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Section 5 – 510(k) Summary

Device Name: Cydar EV

K160088

1. 1. **Submission Sponsor**

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2. **Submission Correspondent**

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3. Date Prepared

24 May 2016

4. Device Identification

Trade/Proprietary Name:	Cydar EV
Common/Usual Name:	Interventional Fluoroscopic X-Ray System
Classification Name:	Interventional Fluoroscopic X-Ray System
Regulation Number:	892.1650
Product Code:	OWB, Interventional Fluoroscopic X-Ray System
Device Class:	Class II
Classification Panel:	Radiology

5. Legally Marketed Predicate Device

K151598 – VesselNavigator – Philips Medical Systems Nederland B.V.

6. 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 provides augmented reality enhanced X-ray fluoroscopy images for use during X-ray guided surgery.

Cydar EV is a software only medical device. It defines minimum requirements to the hardware it runs on. Access to Cydar EV will be effected by a secure connection over either private networks or the public Internet.

The cloud communication, storage and processing solution is operated and maintained by specially trained Cydar Ltd staff and is based on the Ubuntu Linux operating system (versions 12.4 and 14.4). The client machines are based on Microsoft Windows 8.1, running the Google Chrome web-browser (version 47) and equipped with a video framegrabber (Foresight AccuStream Express HD+). The client machine captures a live fluoroscopy video feed from the X-rays machine's external (secondary) video port using HDMI, DVI, S-video, or analogue format. Any platform, which complies with the specified minimum hardware and software requirements and with successful system self-test and validation activities can be supported.

The Cydar EV will be marketed as a software only solution for the end-user (with recommended hardware requirements). Any special needs such as integration in a specific environment and updates / upgrades will be covered by individual service contract and fulfilled by specially trained service technicians.

7. Indication for Use Statement

Cydar EV provides image guidance by overlaying preoperative 3D vessel anatomy, from a previously acquired contrast-enhanced, diagnostic CT scan, onto live fluoroscopic images in order to assist in the positioning of guidewires, catheters and other endovascular devices.

Cydar EV 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), 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 the X-ray guided procedures in the liver, kidneys or pelvic organs.

8. Substantial Equivalence Discussion

The following table compares the Cydar EV to the predicate device 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.

Table 5A – Comparison of Characteristics

Manufacturer	**Cydar Ltd**	**Philips Medical Systems Nederland B.V.**	**Significant Differences**
Trade Name	**Cydar EV (Subject device)**	**VesselNavigator (Predicate device)**	
510(k) Number	K160088	K151598	N/A
Product Code	OWB	OWB / LLZ	Similar; the Product Code LLZ is not considered as product is not a PACS system
Regulation Number	892.1650	892.1650 / 892.2050	Similar; the regulation number 892.2050 is not considered as product is not a PACS system
Regulation Name	Interventional Fluoroscopic X-Ray System	Interventional Fluoroscopic X-Ray System / Picture Archiving and	Similar; the regulation number

Manufacturer	**Cydar Ltd**	**Philips Medical Systems Nederland B.V.**	**Significant Differences**
Trade Name	**Cydar EV** **(Subject device)**	**VesselNavigator** **(Predicate device)**	
		Communications System	892.2050, PACS, is not considered as product is not a PACS system
Intended use	Display of combined live 2D X-ray fluoroscopy and 3D anatomy for image guidance during surgery.	Display of combined live 2D X-ray fluoroscopy and 3D anatomy for image guidance during surgery.	Identical
3D imaging	Pre-operative	Pre-operative	Identical
X-ray fluoroscopy	Live	Live	Identical
Indications for Use	Cydar EV provides image guidance by overlaying preoperative 3D vessel anatomy, from a previously acquired contrast-enhanced, diagnostic CT scan, onto live fluoroscopic images in order to assist in the positioning of guidewires, catheters and other endovascular devices. Cydar EV 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), angioplasty, stenting and embolization in the common iliac, proximal external iliac and proximal internal iliac arteries and corresponding	VesselNavigator provides image guidance by superimposing live fluoroscopic images on a 3D volume of the vessel anatomy to assist in catheter maneuvering and device placement. VesselNavigator is intended to assist in the treatment of endovascular diseases during procedures such as (but not limited to) AAA, TAA, carotid stenting, iliac interventions.	Similar; indications for both devices emphasize image guidance for fluoroscopy-guided endovascular procedures

Manufacturer	Cydar Ltd	Philips Medical Systems Nederland B.V.	Significant Differences
Trade Name	**Cydar EV (Subject device)**	**VesselNavigator (Predicate device)**	
	veins. Cydar EV is not intended for use in the X-ray guided procedures in the liver, kidneys or pelvic organs.		
Construction	Software product	Software product	Identical
Host computer	Separate interventional tools workstation	Separate interventional tools workstation	Identical
Registration Overview	2D-3D registration is achieved by machine vision tracking of vertebral anatomy	2D-3D registration is achieved by manual initialization and/or correction followed by dead reckoning based on electromechanical tracking of table and C-arm	Different; the predicate and subject devices use different methods to perform the underlying 2D-3D image registrations though viewing of the image overlay functionality is then performed the same with no additional questions raised for safety or efficacy
Registration target	Vertebral anatomy	X-ray C-arm and operating table	Different; targets reflect different registration methods with the image overlay functionality being the same with no additional questions raised for safety or efficacy
Patient contacting	No	No	Identical

Manufacturer	**Cydar Ltd**	**Philips Medical Systems Nederland B.V.**	**Significant Differences**
Trade Name	**Cydar EV (Subject device)**	**VesselNavigator (Predicate device)**	
Energy emitted or absorbed	No	No	Identical
Dynamic update on C-arm / table motion	Automatic	Automatic	Identical
Dynamic update on patient motion	Automatic	Semi-automatic based on movement of the gantry	Similar; automatic response to patient motion allows registration to continuously occur with no additional questions raised for safety or efficacy
Anatomical Location	Vascular anatomy of the chest, abdomen and pelvis.	All vascular anatomy except coronaries and intracranial vessels	Similar; the subject device is restricted to anatomy considered immobile with respect to the vertebral column with no additional questions raised for safety or efficacy
Ability to store roadmaps	Yes	Yes	Identical
Ability to store snapshots	Yes	Yes	Identical
Non-clinical performance data			
IEC 62304	Applied	Applied	Identical
IEC 62366	Applied	Applied	Identical

Manufacturer	Cydar Ltd	Philips Medical Systems Nederland B.V.	Significant Differences
Trade Name	**Cydar EV (Subject device)**	**VesselNavigator (Predicate device)**	
ISO 14971	Applied	Applied	Identical
NEMA PS 3.1-3.20 DICOM	Applied	Applied	Identical

9. Non-Clinical Performance Data

As part of demonstrating the safety and effectiveness of Cydar EV and in showing substantial equivalence to the predicate device that is the subject of this 510(k) submission, Cydar Ltd completed a number of non-clinical performance tests. The Cydar EV meets all the requirements for overall design confirming that the design output meets the design inputs and specifications for the device.

Non-clinical performance testing has been performed on Cydar EV and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- IEC 62304:2015 Medical device software – Software life cycle processes
- IEC 62366-1:2015 Medical devices – Application of usability engineering to medical devices
- ISO 14971:2007 Medical devices – Application of risk management to medical devices
- NEMA PS 3.1-3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2011)
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005).

Software verification testing has been performed in accordance with the software verification plan to cover the system requirements at system/integration and unit levels as documented in this submission as well as the identified hazard mitigations. Software verification included:

- registration accuracy calculated from images of the vertebral anatomy as documented in Varnavas A, Carrell T, Penney G. “Fully automated 2D–3D registration and verification” Medical Image Analysis 26 (2015):1 08–119, and
- overlay alignment accuracy in the web browser display, and
- information security, and
- responsiveness of overlays to changes in the fluoroscopy imagery.

Software validation testing has been performed in accordance with the software validation plan and included:

- the intended use and commercial claims, and usability testing with representative clinical users considering:
    - ease of use,
    - visibility and legibility of displays and overlays
- usability testing with system operators and IT staff,
- testing of the vessel segmentation tool,
- system availability and up-time.

All of these tests were used to support substantial equivalence of the subject device.

The test results in this 510(k) premarket notification demonstrate that Cydar EV:

- complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance document, and
- meets the acceptance criteria and is adequate for its intended use.

Therefore, Cydar EV is substantially equivalent to the currently marketed predicate device VesselNavigator in terms of safety and effectiveness.

10. Clinical Performance Data

A clinical investigation was conducted to evaluate safety and efficacy of the Cydar EV to provide image guidance by overlaying preoperative (diagnostic) 3D vessel anatomy onto live fluoroscopic images in order to assist in the positioning of guidewires, catheters and other endovascular devices. Cydar EV is intended to assist fluoroscopy-guided endovascular procedures in the chest, abdomen and pelvis. Suitable procedures include (but are not limited to) endovascular aortic aneurysm repair (TAA and AAA), iliac (arterial and venous) angioplasty, stenting and embolisations. The design was a multi-centre observational study examining safety, performance, usability, and clinical effect. The overall design of the clinical study is shown as follows:

- Clinical Endpoints: Primary endpoints were the accuracy, robustness, usability, procedure time, radiation exposure, and iodinated contrast volume
- Subject Inclusion/Exclusion: The trial participants were patients who:
    - were willing and able to give informed consent, and
    - were aged 18 or older, and
    - were scheduled to undergo an X-ray guided intervention in an anatomic zone covered by the technology, and
    - had had a pre-operative CT scan, and
    - were able and willing to comply with the study requirements.
- Study Monitoring: Cloud monitoring and data collection was performed by Cydar Ltd

The clinical endpoint and user feedback data supported the hypothesis of clinical effectiveness. Results of the clinical investigation support the indications for use of the Cydar EV to provide image guidance by overlaying preoperative (diagnostic) 3D vessel anatomy onto live fluoroscopic images in order to assist in the positioning of guidewires, catheters and other endovascular devices by achieving accurate, robust, and usable image guidance. Clinical study conclusion confirms that the device is safe and effective as used according to the instructions for use.

11. Statement of Substantial Equivalence

The Cydar EV, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.