DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Therenva SAS
% Mr. Matthis Hamy
QA & RA Manager
4 rue Jean Jaures
Rennes, 35000
FRANCE

September 21, 2017

Re: K171829
Trade/Device Name: EndoNaut
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB
Dated: August 25, 2017
Received: August 31, 2017

Dear Mr. Hamy:

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 (DICE) 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 (DICE) 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,

Michael D. O'Hara For

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)*

K171829

Device Name
EndoNaut

Indications for Use *(Describe)*

EndoNaut provides image guidance by overlaying preoperative 3D vessel anatomy onto live fluoroscopic images in order to assist in the positioning of the guidewires, catheters and other endovascular devices.

EndoNaut is intended to assist endovascular procedures in the thorax, abdomen, neck, pelvis and lower limbs. Suitable procedures include (but not limited to) endovascular aortic aneurysm repair (AAA and TAA), angioplasty, stenting and embolization in iliac arteries and corresponding veins.

EndoNaut 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 - EndoNaut 510(K) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 CFR Part 807.92(c)

Therenva SAS hereby submits this traditional 510(k) to provide a notification submission for a new device

1. Submitter information

Manufacturer Name:	Therenva SAS 4, rue Jean Jaurès 35000 Rennes France
Contact Person:	Matthis Hamy, QA & RA Manager Phone: +33 6 06 86 16 86 E-mail: matthis.hamy@therenva.com
Establishment Registration Number:	3011240766
Date prepared:	05/31/2017

2. Device Identification

Device Trade Name:	EndoNaut
Device Common Name:	Interventional Fluoroscopic X-ray System
Regulation Class:	Class II (21 CFR 892.1650, OWB)
Classification Name:	Interventional Fluoroscopic X-ray System
Classification Panel:	Radiology

3. Predicate Device Identification

Device Classification Name:	Interventional Fluoroscopic X-ray System
Regulation Number:	892.1650
510(k) Number:	K160088
Device Name:	Cydar EV
Product Code:	OWB, Interventional Fluoroscopic X-ray System

Decision:	SUBSTANTIALLY EQUIVALENT (SE)

4. Device Description

EndoNaut is a stand-alone software medical device that runs on a Windows based computer that meets the minimum requirements.

EndoNaut software provides navigation tools for image-guided endovascular surgery. The device enables to register the X-ray intra-operative images and the pre-operative data.

The device is operated by the physician or a trained operator. The client machine captures a live fluoroscopy video feed from the X-ray's machine external video port, either in digital or in analog format. Any machine that meets the hardware and software requirements can be supported.

The EndoNaut will be marketed as a software only solution.

5. Indications for Use

EndoNaut provides image guidance by overlaying preoperative 3D vessel anatomy onto live fluoroscopic images in order to assist in the positioning of the guidewires, catheters and other endovascular devices.

EndoNaut is intended to assist endovascular procedures in the thorax, abdomen, neck, pelvis and lower limbs. Suitable procedures include (but not limited to) endovascular aortic aneurysm repair (AAA and TAA), angioplasty, stenting and embolization in iliac arteries and corresponding veins.

EndoNaut is not intended for use in the X-ray guided procedures in the liver, kidneys or pelvic organs.

6. Predicate Device Comparison

EndoNaut has similar indications for use, principle of operation and technical characteristics than the predicate device listed above. The differences between the devices do not raise any question with respect to the safety and effectiveness of the subject device.

Comparison table:

Manufacturer	Therenva SAS	Cydar Ltd	Differences
Device Name	**EndoNaut (Subject Device)**	**Cydar EV (Predicate Device) K160088**	
Product Code	OWB	OWB	Identical
Regulation Number	892.1650	892.1650	Identical
Regulation Name	Interventional Fluoroscopic X-Ray System	Interventional Fluoroscopic X-Ray System	Identical
Indications for Use	EndoNaut provides image guidance by overlaying preoperative 3D vessel anatomy onto live	Cydar EV provides image guidance by overlaying preoperative 3D vessel anatomy, from a previously	Similar. Both devices are image guidance systems for fluoroscopy-

Manufacturer	Therenva SAS	Cydar Ltd	Differences
Device Name	**EndoNaut (Subject Device)**	**Cydar EV (Predicate Device) K160088**	
	fluoroscopic images in order to assist in the positioning of the guidewires, catheters and other endovascular devices. EndoNaut is intended to assist the treatment of endovascular diseases during procedures such as (but not limited to) AAA, TAA, carotid stenting, iliac interventions. EndoNaut is not intended for use in the X-ray guided procedures in the liver, kidneys or pelvic organs.	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.	guided endovascular procedures.
Hardware	Software only product; runs on a separate interventional tools workstation.	Software only product; runs on a separate interventional tools workstation.	Identical
Registration Overview	2D-3D registration is achieved by manual initialization and machine vision tracking of vertebral anatomy	2D-3D registration is achieved by machine vision tracking of vertebral anatomy	Similar. The manual initialization in EndoNaut allows securing and improving the registration algorithm. 2D-3D registration is performed the same with no questions raised

Manufacturer	Therenva SAS	Cydar Ltd	Differences
Device Name	**EndoNaut (Subject Device)**	**Cydar EV (Predicate Device) K160088**	
			for safety and effectiveness.
Registration target	Vertebral anatomy	Vertebral anatomy	Identical
Patient contacting	No	No	Identical
Energy emitted or absorbed	No	No	Identical
Dynamic update on C-arm / table / patient motion	Automatic motion detection; registration is updated manually.	Automatic	Different. In the subject device, the registration is updated through a semi-automatic workflow with no additional questions raised for safety and effectiveness.
Anatomical Location	Vascular anatomy of the chest, abdomen, pelvis and lower limbs.	Vascular anatomy of the chest, abdomen and pelvis.	Similar. The subject device includes guidance tools for lower limbs similar than for aortic region, with no additional questions raised for safety and effectiveness.
Ability to store roadmaps	Yes, in Lower Limbs module only	Yes	Similar. Ability to store roadmaps does not impact the intended use and does not raise additional questions for safety and effectiveness
Ability to store snapshots	Yes	Yes	Identical

Manufacturer	Therenva SAS	Cydar Ltd	Differences
Device Name	**EndoNaut (Subject Device)**	**Cydar EV (Predicate Device) K160088**	
IEC 62304	Applied	Applied	Identical
IEC 62366	Applied	Applied	Identical
ISO 14971	Applied	Applied	Identical
NEMA PS 3.1-3.20 DICOM	No	Applied	Different. The subject device does not connect to the PACS. Input patient data are provided through EndoSize software (K160376), DICOM compliant, with no additional question raised for safety and effectiveness

7. Performance Data

Non-clinical performance testing has been performed and demonstrates compliance with following standards:

- ISO 14971 – Medical Devices – Application of risk management to medical devices
- IEC 62304 – Medical Devices software – Software life-cycle processes
- IEC 62366 – Medical Devices – Application of usability engineering to medical devices
- 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 and validation testing includes:

- Verification and validation of system, user requirements and hazard mitigations through use case scenarios,

- Usability testing with representative clinical users considering ease of use, intuitiveness and visibility of data,

- Verification and Validation of registration accuracy:
    - Acceptance criteria: registration error less than 3mm

- Methodology: 5000 different registrations have been performed on 100 peroperative CT-scan images from 50 patients undergoing EVAR procedure. Results have been compared to a gold standard transformation matrix
- Results: meet the acceptance criteria

- Verification and Validation of panorama creation: quantification of parallax and X-ray panorama errors on in-vivo data
  - Acceptance criteria: max acceptable error of 10mm for peripheral artery surgery
  - Methodology: on 7 cases (6 patients and 1 phantom), comparison between panoramas generated by EndoNaut and a perfect panorama (manually corrected)
  - Results: mean errors below the acceptance criteria

- Verification and Validation of measuring functions of EndoNaut:
  - Acceptance criteria: No error for distance measurement along centreline. Max error 1mm for length measurements on images.
  - Methodology: comparison between centerline measurements given by EndoSize (planning tool) and EndoNaut. Comparison between length measurements given by EndoNaut and a visible rule on the fluoroscopic image.
  - Results: meet the acceptance criteria

The test results in this 510(k) demonstrate that EndoNaut complies with the aforementioned international and FDA-recognized consensus standards, and meets the acceptance criteria and is adequate for its intended use.

8. Clinical Data

A clinical investigation was conducted to evaluate safety and efficacy of the EndoNaut to provide image guidance by overlaying preoperative 3D vessel anatomy onto live fluoroscopic images in order to assist in the positioning of guidewires, catheters and other vascular devices.

The study was a single-centre, prospective, consecutive feasibility pilot study. The objectives were to evaluate the feasibility of fusion imaging during aortic endovascular procedures using EndoNaut software, and to evaluate the efficiency of the device when deploying infrarenal aortic stent grafts to treat unruptured atheromatous aneurysms (EVAR).

- Clinical Endpoints: Primary endpoint was the feasibility rate of fusion. Secondary endpoints were radiation dose as measured by fluoroscopy time, dose-area product and air kerma.
- Inclusion criteria:
  - Patients eligible for endovascular treatment of aneurysm disease of the aorta.
  - Patients who received written and verbal information about the protocol and did not object to participating in the trial.
- Exclusion criteria:
  - Patients who also required a conventional surgical revascularisation procedure or who required an endovascular revascularisation procedure in another site.
  - Patients who underwent MR angiography during preoperative evaluation.
  - Non-analysable CT angiogram (no or poor injection).
  - Procedure performed in a hybrid room or in an operating room not equipped with a mobile flat-panel detector.

Results of the clinical study support the indications for use of the EndoNaut to provide image guidance by overlaying preoperative 3D vessel anatomy onto live fluoroscopic images. Clinical study conclusion confirms that the device is safe and effective as used according to the instructions for use.

9. Substantial Equivalence Conclusion

The EndoNaut software is substantially equivalent to the predicate device in terms of intended use, indications for use and technical characteristics. The EndoNaut software has successfully undergone every bench testing.

Based on the information supplied in this 510(k), Therenva SAS concludes that EndoNaut is substantially equivalent to the predicate device and is safe and effective.