October 25, 2022

Therenva SAS
% Cemil Goksu
CEO
74F rue de Paris
Rennes, 35000
FRANCE

Re: K222070
Trade/Device Name: EndoNaut
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, LLZ
Dated: September 23, 2022
Received: September 23, 2022

Dear Cemil Goksu:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222070

Device Name
EndoNaut

Indications for Use *(Describe)*

EndoNaut is an image fusion software solution and computerized navigational system intended to assist X-ray fluoroscopy-guided procedures in the positioning of surgical instruments and endovascular devices.

EndoNaut is indicated for use by Physicians for patients undergoing a fluoroscopy X-ray guided procedure in the chest, abdomen, pelvis, neck and lower limbs, such as aneurysm repair, artery/vein embolization, or peripheral artery disease treatment.

The information provided by the software or system is in no way intended to substitute for, in whole or in part, the surgeon's judgment and analysis of the patient's condition.

It is mandatory to check the real-time anatomy with a suitable imaging technique, such as a contrast-enhanced 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.

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EndoNaut Traditional 510(K) Summary

1. Submitter information

Manufacturer Name: Therenva SAS
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France

Contact Person: Mrs Audrey Gallois, QA & RA Leader
Phone: +33 6 86 95 44 39
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Establishment Registration N°: 3011240766

Date prepared: 25/10/2022

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2. Device Identification

Trade Name:	EndoNaut
Regulation Name:	Interventional Fluoroscopic X-ray System
Regulatory Class:	Class II
Product Code:	OWB (Interventional Fluoroscopic X-ray System)(Primary) LLZ (System, Image Processing, Radiological)(Secondary)
Classification Regulation:	21 CFR 892.1650 and 21 CFR 892.2050
Classification Panel:	Radiology
Accessories:	1. Workstation for navigation tools ("EndoNaut Workstation") 2. EndoSize Software 3. EndoNaut Server Main Display SW

3. Predicate device and accessories

Predicate medical device name	Manufacturer	510K number
EndoNaut	Therenva	K212383

Predicate accessory name	Manufacturer	510K number
EndoNaut workstation Model: TS1CA2DS1-2	Therenva	referred to in K212383 510(k) submission
EndoSize	Therenva	K160376 also referred to in K212383 510(k) submission
EndoNaut Server Main Display SW	Therenva	No prior 510(k) clearance

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4. Description of the device

EndoNaut is a computerized navigation system consisting of a software part that carries the medical features and technologies that are controlled and can be installed on a hardware part that enables the medical device to be used in accordance with its intended purpose.

EndoNaut is intended to assist X-ray fluoroscopy-guided procedures in the positioning of surgical instruments and endovascular devices.

EndoNaut Software parts are supported by hardware and software accessories which enable image display and an interaction with the user.

The Software part is interoperable with EndoSize which is a standalone Software designed and developed by Therenva to enable case planning strategy and device (endoprosthesis) selection be-fore endovascular procedure. EndoSize is used by practitioners (in the preparation phase of the operating procedure) or by endoprosthesis manufacturers to visualize vascular structures and/or carry out an extract of the vascular structure from the preoperative CT scan. EndoSize is medical device software which obtained a substantial equivalence determination and FDA clearance through the CDRH pre-market notification process (510(K)) (N°K160376).

5. Indications for use

EndoNaut is an image fusion software solution and computerized navigational system intended to assist X-ray fluoroscopy-guided procedures in the positioning of surgical instruments and endovascular devices.

EndoNaut is indicated for use by Physicians for patients undergoing a fluoroscopy X-ray guided procedure in the chest, abdomen, pelvis, neck and lower limbs, such as aneurysm repair, artery/vein embolization, or peripheral artery disease treatment.

The information provided by the software or system is in no way intended to substitute for, in whole or in part, the surgeon's judgment and analysis of the patient's condition.

It is mandatory to check the real-time anatomy with a suitable imaging technique, such as a contrast-enhanced angiography, before deploying any invasive medical device.

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6. Comparison to the cleared (legacy) device and substantial equivalent discussion

Medical Device Software Name	**EndoNaut (Predicate Device) K212383**	**EndoNaut (Subject Device)**	**Comparable Properties an Substantial Equivalence Discussion**
System Trade (and Common) Name	EndoNaut System	EndoNaut System	Identical Two new system configurations have been added (MHS and FHS). The tests carried out and the risk analyses did not reveal any particular risk and validated the safety and performance of the systems.
Medical Device Software Trade Name	EndoNaut	EndoNaut SW	**Similar** Because a new variant of EndoNaut Software is introduced, we introduce a new naming convention to avoid confusion between EndoNaut (Standalone) SW and EndoNaut (Server) SW. The naming convention is detailed in Section 6 (EndoNaut System Device Description). No risk related to identification between the two software variants.
Manufacturer	Therenva SAS	Therenva SAS	Identical
Accessory 1	EndoNaut Workstation	EndoNaut Workstation	**Minor change** See below "Workstation cart"
Accessory 2	EndoSize Software (K160376)	EndoSize Software (K160376)	Identical Therefore, substantially equivalent.
Accessory 3	EndoNaut Workstation Main Display	EndoNaut Server Main Display	**New**
Identification and traceability (UDI)	EndoNaut (system): **3760262480046** EndoNaut SW (Standalone): **3760262480022**	EndoNaut (system) (Variant 1 = EndoNaut SW + EndoNaut Workstation): **3760262480046** EndoNaut System MHS: **3760262480084** EndoNaut System FHS: **3760262480077** EndoNaut (Standalone)SW:	**Similar** No risk related to identification between EndoNaut medical device software/system because different UDI-DIs are allocated. No risk related to identification of EndoNaut System because different UDI-DIs are allocated.

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Medical Device Software Name	**EndoNaut (Predicate Device) K212383**	**EndoNaut (Subject Device)**	**Comparable Properties an Substantial Equivalence Discussion**
	EndoNaut Workstation TS1CA2DS1-2: **3760262480039**	**3760262480022** EndoNaut (Server) SW: **3760262480053** EndoNaut Workstation TS1CA2DS1-2: **3760262480039** EndoNaut Server Main Display SW: **3760262480091**	New UDI-DI allocated to EndoNaut SW medical device software variant, EndoNaut Server and its new accessory EndoNaut Server Main Display See also "Labelling" here after.
Software versioning	2-level versioning Version x.y	3-level versioning Version x.y.z	**Similar** Adoption of a more traditional versioning system more commonly applied by software publishers to EndoNaut (Server) SW and EndoNaut Server Main Display SW. This change did not raise any particular risk nor questions of safety and effectiveness.
Product Code	OWB	OWB (Primary product code), LLZ (Secondary product code)	**Similar** OWB is used as Primary product code in reference to our original predicates but in no case does EndoNaut produce x-rays. LLZ product code is much more relevant.
Regulation Number	892.1650	892.1650 892.2050	**Similar** Secondary code added.
Regulation Names	Interventional Fluoroscopic X-Ray System	Interventional Fluoroscopic X-Ray System Medical Image Management and Processing System	**Similar** Regulation name of secondary code added which is more adequate for our advanced medical imaging device.
Software Safety class (62304)	B	B	Identical Therefore, substantially equivalent.
Level of concern	Moderate	Moderate	Identical Therefore, substantially equivalent.
Intended use	EndoNaut provides image guidance by overlaying preoperative 3D vessel anatomy onto live fluoroscopic images in order to assist in the	EndoNaut is an image fusion software solution and computerized navigational system intended to assist X-ray fluoroscopy-guided	**Similar** Minor rewording of the Intended Use has been made to facilitate the understanding by the users and recipients of

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Medical Device Software Name	EndoNaut (Predicate Device) K212383	EndoNaut (Subject Device)	Comparable Properties an Substantial Equivalence Discussion
	positioning of the guide-wires, catheters and other endovascular devices.	procedures in the positioning of surgical instruments and endovascular devices.	the information but also to make the "imaging input data" consistent with the "indications for use". The general purpose of the device and its function remain unchanged. The minor rewording of the Intended Use does not raise different questions of safety and effectiveness.
Indications for use	EndoNaut is indicated for the treatment of patients with endovascular diseases and who needs for example (without this list being restrictive): • endovascular aortic aneurysm repair (AAA and TAA), • angioplasty, • stenting, • embolization in iliac arteries and corresponding veins. EndoNaut is indicated for endovascular procedures in the thorax, abdomen, pelvis and lower limbs.	EndoNaut is an image fusion software solution and computerized navigational system intended to assist X-ray fluoroscopy-guided procedures in the positioning of surgical instruments and endovascular devices. EndoNaut is indicated for use by Physicians for patients undergoing a fluoroscopy X-ray guided procedure in the chest, abdomen, pelvis, neck and lower limbs, such as aneurysm repair, artery/vein embolization, or peripheral artery disease treatment. The information provided by the software or system is in no way intended to substitute for, in whole or in part, the surgeon's judgment and analysis of the patient's condition. It is mandatory to check the real-time anatomy with a suitable imaging technique, such as a contrast-enhanced angiography, before deploying any invasive medical device.	**Similar** Without being a X-ray device itself, as a matter of principle, EndoNaut works with fluoroscopic images to produce image fusion. The clear reference to X-ray guided procedures aims at providing more transparency. Conditions and anatomical locations are the same, just written in a slightly different way.

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Medical Device Software Name	EndoNaut (Predicate Device) K212383	EndoNaut (Subject Device)	Comparable Properties an Substantial Equivalence Discussion
Labelling	1 label in the "about" section for the Medical Device Software with the Trade Name "EndoNaut Software". + 1 label on the workstation with the Trade Name "EndoNaut" (for the whole System) and Workstation model Number = TS1CA2DS1-2 + unique Serial (production) Number (for the whole System)	For EndoNaut System: 1 label in the "about" section for the Medical Device Software with the Trade Name "EndoNaut Software". + 1 label on the workstation with the Trade Name "EndoNaut" (for the whole System) and Workstation model Number = TS1CA2DS1-2 + unique Serial (production) Number (for the whole System) For EndoNaut Server: 1 label in the "about" section for the Medical Device Software server with the Trade Name "EndoNaut Server".	Identical (EndoNaut Software and EndoNaut Workstation) **New** The label on the new Software variant follows the same rule as for EndoNaut Software. As EndoNaut Server has no user interface, if it is integrated into a System, it will keep its own labelling and the labelling of the System will be indicated on another component of the System (a client for example). This will be done under the responsibility of the integrator.
Directions for use (User Guide(s))	1 User Guide for EndoNaut Software 1 User Guide for EndoNaut Workstation + 1 addendum for informing about the conditions governing the marketing of EndoNaut.	**For EndoNaut System:** 1 User Guide for EndoNaut Software 1 User Guide for EndoNaut Workstation + 1 addendum for informing about the conditions governing the marketing of EndoNaut System. **For EndoNaut System composed of EndoNaut (Server) SW:** Integration manual, Communication Protocol and Developer Documentation.	Slight changes to EndoNaut Standalone SW IFU only following minor SW release. No change to EndoNaut Workstation IFU. **New** EndoNaut Server will be provided with an integration manual and Communication Protocol. EndoNaut Server Main Display SW will be provided with an integration manual and Developer Documentation.
Input data	DICOM Images EndoNaut archive produced with Therenva EndoSize Planning Software. C-Arm video stream	DICOM Images EndoNaut archive produced with Therenva EndoSize Planning Software. C-Arm video stream	Similar No new input data. No new features. Only the minimum hardware and software requirements differ slightly due to the

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Medical Device Software Name	EndoNaut (Predicate Device) K212383	EndoNaut (Subject Device)	Comparable Properties an Substantial Equivalence Discussion
	Minimum HW and SW requirements Clinical and performance requirements (display of fusion data, measurements, motion detection, data refresh, interoperability)	Minimum HW and SW requirements Clinical and performance requirements (display of fusion data, measurements, motion detection, data refresh, interoperability)	different deployment configurations. The hardware compatibility evaluation was carried out during the design validation of EndoNaut. The requirements for hardware were also assessed during the clinical protocol by collecting data on hardware used by the surgeon during the study. The difference did not raise any risk nor safety or performance concerns.
Output data	Verified and validated features (Image visualization, measurements, fusion, registration, motion detection, contrast detection) Code and technical documentation	Verified and validated features (Image visualization, measurements, fusion, registration, motion detection, contrast detection)	Similar V&V's activities demonstrate an equivalent level of performance of the EndoNaut. For its server version, due to the different architecture, in some cases (recalibration in particular) we even note a gain in terms of execution speed. No unacceptable risk for the security of users, patients or IT has been identified. No changes were made to production methods, code review and associated documentation. The outputs produced are compliant with the standards.

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Medical Device Software Name	**EndoNaut (Predicate Device) K212383**	**EndoNaut (Subject Device)**	**Comparable Properties an Substantial Equivalence Discussion**
Machine-Learning algorithms	The algorithms are carried by the EndoNaut software only. Features which call machine-learning algorithms: • Registration 3D/2D • Motion detection • Contrast injection detection	The algorithms are carried by the EndoNaut (standalone and server) software only. Features which call machine-learning algorithms: • Registration 3D/2D • Motion detection • Contrast injection detection	Similar The algorithms have not been changed. Only the way they are implemented is different between the EndoNaut Standalone Software and the EndoNaut Server Software (different architectures). These implementation changes do not change the purpose of the algorithms (they do what they did before). The validation carried out raised no additional questions for safety and effectiveness.
Hardware compatibility	EndoNaut Software is the class II medical device Software which runs on a separate interventional tools (imaging) workstation, the so-named EndoNaut Workstation which is the accessory of the medical device software.	EndoNaut system consists of • a software part that carries the medical features and technologies that are controlled and • a hardware part that enables the medical device to be used in accordance with its intended purpose. The hardware part can be: o the EndoNaut Workstation or o a computer meeting the minimum Hardware and Software requirements for EndoNaut standalone SW or EndoNaut Server. The Hardware part must be compliant with the US regulations.	Similar Hardware and Software requirements have been adjusted to EndoNaut Server and are indicated in the Directions for use as a prerequisite. V&V activities didn't show any risk or failure. No additional questions raised for safety and effectiveness.
Software Operating System	Windows 10 64 bits	Windows 10 64 bits	Identical Therefore, substantially equivalent.
Software interoperability	EndoNaut requires the use of EndoSize software (K160376) to prepare patient	EndoNaut is interoperable with the EndoSize software (K160376) which is designed to prepare patient	Similar as regards EndoSize and New for EndoNaut (Server) SW and EndoNaut Server Main Display SW

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Medical Device Software Name	EndoNaut (Predicate Device) K212383	EndoNaut (Subject Device)	Comparable Properties an Substantial Equivalence Discussion
	data and perform preoperative sizing. Data imported from EndoSize include 3D volume, preoperative images, sizing report (comments and measurements), and snapshots taken during sizing.	data and perform pre-operative sizing. Data imported from EndoSize include 3D volume, preoperative images, sizing report (comments and measurements), and snapshots taken during sizing. EndoNaut Server does not have a user interface. The User interface is provided by the clients. External interface with clients is provided through a communication protocol.	Some clarifications are made. Preoperative data is a mandatory input for the use of AI features, but it is not for the PAD features. Preoperative data include pre-op CT images and sizing report (in case of AI procedures). The stent placement strategy and sizing are usually performed pre-operatively via the use of software devices such as EndoSize. Alternatives to EndoSize exist: other sizing or visualization software. In such cases, the data is then printed on paper and used in the operating room as is. The communication protocol of EndoNaut (Server) SW did not raise any risk nor safety or performance concerns.
Visualization	Intra-operative fluoroscopy or angiography, pre-operative CT scan image, pre-operative 3D scanner volume reconstruction (if any in case of PAD procedures). For AI procedures: Before and during the intervention, the user can access information from pre-operative sizing report such as pre-op CT images, measurements, comments, snapshots and strategy.	Intra-operative fluoroscopy or angiography, pre-operative CT scan image, pre-operative 3D scanner volume reconstruction (if any in case of PAD procedures). For AI procedures: Before and during the intervention, the user can access information from pre-operative sizing report such as pre-op CT images, measurements, comments, snapshots and strategy.	Identical
Export	Take and export snapshots. Export panoramas in case of PAD module.	Take and export snapshots. Export panoramas in case of PAD module.	Identical Therefore, substantially equivalent.

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Medical Device Software Name	EndoNaut (Predicate Device) K212383	EndoNaut (Subject Device)	Comparable Properties an Substantial Equivalence Discussion
3D-2D / 2D-2D Registration	Display 2D-3D fusion: 3D volume pre-op overlay on per-op 2D fluoroscopy. Semi-automatic registration (automatic or manual initialization, automatic computation and manual validation). Panorama creation: Acquisition and save of fluoroscopy and angiography stage by stage keeping the same C-Arm orientation. Display 2D-2D fusion: 2D pre-op angiographic overlay on per-op 2D fluoroscopy. Synchronization between current per-op 2D fluoroscopy and 2D fluoroscopy from recorded panorama.	Display 2D-3D fusion: 3D volume pre-op overlay on per-op 2D fluoroscopy. Semi-automatic registration (automatic or manual initialization, automatic computation and manual validation). Panorama creation: Acquisition and save of fluoroscopy and angiography stage by stage keeping the same C-Arm orientation. Display 2D-2D fusion: 2D pre-op angiographic overlay on per-op 2D fluoroscopy. Synchronization between current per-op 2D fluoroscopy and 2D fluoroscopy from recorded panorama.	Identical
Dynamic update on C-arm / table / patient motion	Automatic motion detection Registration: automatic/manual initialization and manual user validation.	Automatic motion detection Registration: automatic/manual initialization and manual user validation.	**Similar** Slight change for EndoNaut (Standalone) SW: The registration workflow is modified to be more consistent with clinical expectations. The possibility to start again a registration in automatic mode is offered instead of switching to semi-automatic mode after a first try in automatic mode. The way the automatic mode works and its performance, safety characteristics are unchanged. Without any change being made to the automatic mode (so no impact on safety or performance, risks), users have the possibility to adapt the image received from the CArm to display more bone structures for example. Once he relaunches the registration in automatic mode, it

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Medical Device Software Name	EndoNaut (Predicate Device) K212383	EndoNaut (Subject Device)	Comparable Properties an Substantial Equivalence Discussion
			may get better results at the end of the registration process. For EndoNaut (Server) SW: These features have been transferred in the new software architecture. Final validation is always required. It is implemented at the integrator's discretion via the SYNC_CT_ACCEPT command. New risks due to the new software architecture have been addressed. New clinical data were not necessary. V&V activities were performed and successful. No additional questions raised for safety and effectiveness.
Patient contacting	No	No	Identical
Energy emitted or absorbed	No	No	Identical
Workstation main display & computer	Panel PC ACL OR-PC 27LP Rated AC 100-240V, 1.5-0.6 A ~47 – 63 Hz Monitor size: 27'' LCD Brightness: 300 cd/m2 Resolution: 1920 x 1080 Cooling Fanless (no maintenance)	Panel PC ACL OR-PC 27LP Rated AC 100-240V, 1.5-0.6 A ~47 – 63 Hz Monitor size: 27'' LCD Brightness: 300 cd/m2 Resolution: 1920 x 1080 Cooling Fanless (no maintenance)	Identical
Workstation secondary display (touch screen)	One Touch monitor ELO model 1502L, rated AC 100-240 V Input frequency: 50-60 Hz Monitor size: 15.6'' LCD Native resolution: Full HD : 1920 x 1080 ; HD (WXGA) : 1366 x 768 Brightness: Touch Pro 270 nits Touch technology: PCAP	One Touch monitor ELO model 1502L or 1519LM rated AC 100-240 V Input frequency: 50-60 Hz Monitor size: 15.6'' LCD Native resolution: Full HD : 1920 x 1080 (1502L); HD (WXGA) : 1366 x 768 (1502L, 1519 LM) Brightness: 1502L: Touch Pro 270 nits	Similar Similar for ELO Touch 1502L, one reference added (1519LM) which offers very similar performance. The brightness offered by the ELO 1519LM approaches the full HD ELO 1502L. The slight differences between the two models do not

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Medical Device Software Name	EndoNaut (Predicate Device) K212383	EndoNaut (Subject Device)	Comparable Properties an Substantial Equivalence Discussion
		1519LM: 225 nits Touch technology: PCAP	raise risk, safety nor performance concerns.
Workstation cart	One mobile frame holder ITD, including one isolating transformer, rated AC 115V / 230V 50/60Hz 1240VA	One mobile frame holder ITD, including one isolating transformer, rated AC 115V / 230V 50/60Hz 1240VA.	**Minor change** Change of pro-cart Basic frame: column raised by 16 cm for better visibility. No change of pro-cart supplier. No change of materials. Instability hazards have been evaluated and tested. No confusion possible between the old mobile frame holder and the new mobile frame holder because they are different part reference. No overbalance or hazards that could jeopardize the safety of the users and beneficiaries and call into question the performance of the medical device could be observed.
Workstation dimensions	Height: 1740 mm Width (footprint): 661 (640) mm Depth (footprint): 950 (660) mm Weight: 70 kg	Height: 1850 mm Width (footprint): 661 (640) mm Depth (footprint): 950 (660) mm Weight: 72 kg	Similar Minor dimensional and weight changes do not result in additional risks.
Workstation Connectors	Digital video input: DVI-D or DVI-I* Video output: HDMI Network: 10/100/1000 Mbps Ethernet (RJ45) USB interface USB 3.0 (x2)	Digital video input: DVI-D or DVI-I* Video output: HDMI Network: 10/100/1000 Mbps Ethernet (RJ45) USB interface USB 3.0 (x2)	Identical
Workstation Power supply	Input voltage: 100 – 230 VAC / 50 – 60 Hz	Input voltage: 100 – 230 VAC / 50 – 60 Hz	Identical
Workstation cablings	Connection Box Front cable RJ45 DVI front cable USB 3.0 front cable 1m (x2) Power supplies	Connection Box Front cable RJ45 DVI front cable USB 3.0 front cable 1m (x2) Power supplies	Identical

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Medical Device Software Name	EndoNaut (Predicate Device) K212383	EndoNaut (Subject Device)	Comparable Properties an Substantial Equivalence Discussion
	Power supply extension IEC C7-C14 Power supply extension jack 2.5mm 3m IEC extension cable 1m (red) IEC extension cable 0.5m (blue) External power supply XP POWER (for ELO TOUCH 1502L) External power supply BICKER (for ACL ORPC-27LP) BET-1012M Video cabling: DVI 5m Other cables: HDMI cable 1.5m HDMI/DP adapter USB 3.0 A/B 1m USB 2.0 2m Equipotential 1.5m	Power supply extension IEC C7-C14 Power supply extension jack 2.5mm 3m IEC extension cable 1m (red) IEC extension cable 0.5m (blue) External power supply XP POWER (for ELO TOUCH 1502L) External power supply BICKER (for ACL ORPC-27LP) BET-1012M Video cabling: DVI 5m Other cables: HDMI cable 1.5m HDMI/DP adapter USB 3.0 A/B 1m USB 2.0 2m Equipotential 1.5m	
IEC 62304	Applied	Applied	Identical
IEC 62366	Applied	Applied	Identical
ISO 14971	Applied	Applied	Identical
DICOM Standard parts 1-20	Applied	Applied	Identical
Conformity to IEC 60601-1 of EndoNaut workstation	Yes For CENELEC countries	Yes For CENELEC countries	Identical IEC 60601-1 is not a FDA recognized standard version but is applied and included in V&V protocol and results.
Conformity to ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) of EndoNaut workstation	Yes	Yes	Identical
Conformity to IEC 60601-2 of the separate Workstation for navigation tools	Yes	Yes	Identical IEC 60601-2 FDA recognized standard version is applied and included in V&V protocol and results.
Conformity to IEC 60601-1-6 of EndoNaut workstation	Yes	Yes	Identical IEC 60601-1-6 FDA recognized standard version is applied and included in V&V protocol and results.

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7. Summary of the technical characteristics

EndoNaut (Subject Device) has similar intended use, intended users, indications for use, anatomical location, limitations, patient population, environment of use than the predicate device, EndoNaut (Legacy Device).

EndoNaut workstation TS1CA2DS1-2 has similar material and technical characteristics (design, power, principle of operation) than the predicate accessory, the separate intervention tools workstation TS1CA2DS1-2.

The change of EndoNaut software architecture (monolithic architecture to a server/client architecture) did not fundamentally change the intended use nor the functionalities offered by EndoNaut.

However, Therenva performed a full battery of design, requirement and unit tests and positioned itself in a comprehensive initial review of the risks associated with this change.

The differences between the new modified devices (systems and software) and accessories to their predicates do not raise any question with respect to the safety and effectiveness of the subject device and accessory.

8. Summary of Clinical Performance Data

The subject of this premarket submission did not require clinical studies to support equivalence.

9. Performance Data

EndoNaut does not produce x-rays. EndoNaut may interact with fluoroscopic imaging systems only to retrieve a live video stream using a passive connection or communication protocol, i.e. without returning any data to this system.
Then, EndoNaut does not need to be conform to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard].

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards.

The predicate device (K212383) and the new modified subject device and their respective accessories, the separate interventional tools workstation and EndoSize Software, have been subject to the same Therenva quality assurance system during their design and development:

- Risk assessment
- Usability File Reviews
- Requirement Reviews
- Design Reviews
- Clinical Evaluation Report Reviews

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- Directions for use or Integration manuals Reviews
- Testing on unit level (Module verification)
- Integration testings
- Interoperability testings
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

The same design verification testing including electrical safety, EMC, functional and mechanical testing's were carried out on the new EndoNaut Workstation TS1CA2DS1-2 by the COFRAC accredited testing laboratory. These tests showed that the EndoNaut Workstation TS1CA2DS1-2 meets the design specification and performed as intended.

Verification and validation activities have demonstrated that the EndoNaut (Server) software variant performs equally as the EndoNaut (Standalone) predicate software by providing reliable results, without functional regression and moreover, offers robust safety/security mechanisms.

The devices also demonstrated compliance with the same following standards:

- ISO 14971 – medical devices – Application of risk management to medical devices
- IEC 62304 – medical devices Software – Software life-cycle processes

Specific to EndoNaut Workstation:

- IEC 60601-1 – Medical electrical equipment – Electrical safety
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)
- IEC 60601-2 – Medical electrical equipment – EMC disturbances
- IEC 60601-1-6 – Medical electrical equipment – Usability

10. Statement of substantial equivalence

Based on the information supplied in this Traditional 510(k), Therenva SAS concludes that the EndoNaut (Subject device) is substantially equivalent to the predicate device and accessories with regard to its features, clinical applications and use.

The devices are safe and effective and do not introduce unacceptable risks for the patients nor the users when used as intended and documented by Therenva.