August 31, 2021

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

Re: K212383
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
Dated: July 12, 2021
Received: August 2, 2021

Dear Cemil Göksu:

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 M. Burk -S

Digitally signed by Laurel M. Burk -S
Date: 2021.08.31 10:53:59 -04'00'

, 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)*
K212383

Device Name
EndoNaut

Indications for Use *(Describe)*

EndoNaut is indicated for the treatment of patients with endovascular diseases and who needs, such as but not limited to the following examples:
• 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.

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 Special 510(K) Summary

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

Therenva SAS hereby submits this Special 510(k) to provide a notification submission for a modified device EndoNaut and evidence of substantial equivalence to the Predicate Medical Device EndoNaut (K171829).

The accessories are also subject to this Special 510(k).

## 1. Submitter information

**Manufacturer Name:** Therenva SAS
74F, rue de Paris
35000 Rennes
France

**Contact Person:** Mrs Audrey Gallois, QA & RA Leader
Phone: +33 6 86 95 44 39
E-mail: audrey.gallois@therenva.com

**Establishment Registration N°:** 3011240766

**Date prepared:** 12-Jul-21

## 2. Device Identification

**Trade Name:** EndoNaut

**Regulation Name:** Interventional Fluoroscopic X-ray System

**Regulatory Class:** Class II

**Product Code:** OWB

**Classification Regulation:** 21 CFR 892.1650

**Classification Panel:** Radiology

**Accessories:**

1. Separate interventional tools workstation
2. EndoSize Software

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## 3. Predicate device and accessories

- Predicate Medical Device Software: EndoNaut (K171829)
- Predicate Accessories:
  - Separate interventional tools workstation, TS1CA2DS1-1 (referred to in K171829 510(k) submission) and Cydar Medical's Cydar EV (K160088).
  - EndoSize v3.1 (K160376)

## 4. Description of the device

EndoNaut system is an imaging solution for intraoperative navigation and guidance tool for endovascular procedures (aorto-iliac and peripheral).

EndoNaut provides localization assistance by combining 3D preoperative scans and 2D intra-operative fluoroscopy imagery to help position guides, catheters and other vascular devices.

EndoNaut Software is interoperable with EndoSize which is a standalone Software designed and developed by Therenva to enable case planning strategy and device (endoprosthesis) selection before 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 intended to be used for pre-operational planning and sizing. EndoSize is medical device software which obtained a substantial equivalence determination and FDA clearance through the CDRH premarket notification process (510(K)) (N°K160376).

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

| Medical Device Software Name | **EndoNaut (Predicate Device) K171829** | **EndoNaut (Subject Device)** | **Comparable Properties an Substantial Equivalence Discussion** |
|---|---|---|---|
| Medical Device Software Trade Name | EndoNaut | EndoNaut | Identical |
| Accessory 1 | Separate interventional tools workstation | EndoNaut Workstation | **Different**.<br>Designation adjustment only.<br>We have reclarified the qualification of hardware versus software. By definition, here, the hardware (EndoNaut Workstation) is an accessory to the software medical device. To better differentiate what is applicable to one and the other, we have identified the software by "EndoNaut Software" and the hardware by "EndoNaut Workstation". The EndoNaut Workstation alone is not subject to any regulatory submission. It is integrated with the System submitted for FDA approval under the name, EndoNaut. |
| Accessory 1 Ref. | TS1CA2DS1-**1** | TS1CA2DS1-**2** | **Different**<br>Change of the Panel PC, the Control Panel model and Cablings.<br>Due to these changes, the Product number "TS1CA2DS1-2" has been changed. New testings have been performed. |
| Accessory 2 | EndoSize Software (K160376) | EndoSize Software (K160376) | Identical<br>EndoSize Software is an accessory that is intended to supplement the performance of EndoNaut. |
| Identification and traceability | Name: EndoNaut<br>No UDI | Trade name: EndoNaut<br>Common name: EndoNaut System<br>UDI-DI: 3760262480046 | **Different**<br>No risk related to idenfication between older and newer EndoNaut device.<br>EndoNaut is now referring to the EndoNaut System while the EndoNaut Software is named EndoNaut Software. |

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| Medical Device Software Name | **EndoNaut (Predicate Device) K171829** | **EndoNaut (Subject Device)** | **Comparable Properties an Substantial Equivalence Discussion** |
|---|---|---|---|
| | | | No unit of the predicate device was sold in the USA. |
| Manufacturer | Therenva SAS | Therenva SAS | Identical |
| 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 |
| Software Safety class (62304) | B | B | Identical |
| Level of concern | Moderate | Moderate | Identical |
| Intended use | Intended use and indications for use were mixed.<br>See below Indications for use. | EndoNaut provides image guidance by overlaying pre-operative 3D vessel anatomy onto live fluoroscopic images in order to assist in the positioning of the guidewires, catheters and other endovascular devices. | **Different**<br>A distinction between "Intended use" and "indications for use" has been made based on the recommendations of the FDA Guidance " The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (section IV, D, 1). |
| Indications for use | EndoNaut provides image guidance by overlaying pre-operative 3D vessel anatomy onto live fluoroscopic images in order to assist in the positioning of the guidewires, catheters and other endovascular devices.<br>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.<br>EndoNaut is not intended for use in the X-ray guided procedures in the liver, kidneys or pelvic organs. | EndoNaut is indicated for the treatment of patients with endovascular diseases and who needs for example (without this list being restrictive):<br>• endovascular aortic aneurysm repair (AAA and TAA),<br>• angioplasty,<br>• stenting,<br>• embolization in iliac arteries and corresponding veins.<br><br>EndoNaut is indicated for endovascular procedures in the thorax, abdomen, pelvis and lower limbs. | **Different**<br>A distinction between "Intended use" and "indications for use" has been made based on the recommendations of the FDA Guidance " The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (section IV, D, 1). |

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| Medical Device Software Name | **EndoNaut (Predicate Device) K171829** | **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"<br><br>+<br><br>1 label for the Separate interventional tools workstation with the Trade Name "EndoNaut" and Product Number = TS1CA2DS1-1 + unique Serial (production) Number | 1 label in the "about" section for the Medical Device Software with the Trade Name "EndoNaut Software".<br><br>+<br><br>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) | **Different**<br>Each component of the EndoNaut System has its proper labelling.<br><br>Complete review of Labelling design. Use of symbols of ISO 15223-1.<br>Addition of UDI.<br><br>**Identical**<br>The system has a unique identifier (S/N). |
| Directions for use (User Guide(s)) | 1 User guide for EndoNaut | 1 User Guide for EndoNaut Software<br>1 User Guide for EndoNaut Workstation +<br>1 addendum for informing about the conditions governing the marketing of EndoNaut. | **Different**<br>The directions for use have been enhanced to clearly distinguish the instructions specific to the medical device Software, "EndoNaut SW" from the instructions specific to the EndoNaut Workstation, accessory to EndoNaut SW. |
| Hardware compatibility | Software only product; runs on a separate interventional tools (imaging) workstation. | 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. | **Different**<br>EndoNaut (legacy device) was intended to be sold with and installed on the separate interventional tools workstation (ref: TS1CA2DS1-1) or installed on any hardware meeting the minimum requirements.<br>The conditions for installing the software on the workstation are identical.<br>Only the model number of the workstation has changed (ref: TS1CA2DS1-**2**). |
| Software Operating System | Win Pro 7 SP1x64<br>Win Pro 10 64bits | Win Pro 10 64bits | **Different**<br>Support for Windows 7 ended on January 14, 2020. |

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| Medical Device Software Name | **EndoNaut (Predicate Device) K171829** | **EndoNaut (Subject Device)** | **Comparable Properties an Substantial Equivalence Discussion** |
|---|---|---|---|
| Software interoperability | EndoNaut software requires the use of EndoSize software (K160376) to prepare patient data and perform preoperative sizing.<br>Data imported from EndoSize include 3D volume, preoperative images, sizing report (comments and measurements), and snapshots taken during sizing. | EndoNaut requires the use of EndoSize software (K160376) to prepare patient data and perform preoperative sizing.<br>Data imported from EndoSize include 3D volume, preoperative images, sizing report (comments and measurements), and snapshots taken during sizing. | Similar<br><br>Some clarifications are made.<br>Preoperative data is a mandatory input for the use of AI module, but it is not for the PAD module.<br>Preoperative data include pre-op CT images and sizing report (in case of AI module use).<br><br>The stent placement strategy and sizing are usually performed pre-operatively via the use of software devices such as EndoSize.<br>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. |
| Data management | The user can import and manage patient data within the software. Patient data include pre-op CT images and sizing report. | The user can import and manage patient data within the software. Patient data include pre-op CT images and sizing report. | Similar<br>EndoNaut Software now enables import and export of data with a PACS. |
| Visualization | Intra-operative fluoroscopy or angiography, pre-operative CT scan image, pre-operative 3D scanner volume reconstruction (if any in case of PAD module).<br>AI module only:<br>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 module).<br>AI module only:<br>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.<br>Export panoramas in case of PAD module. | Take and export snapshots.<br>Export panoramas in case of PAD module. | Identical |

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| Medical Device Software Name | **EndoNaut (Predicate Device) K171829** | **EndoNaut (Subject Device)** | **Comparable Properties an Substantial Equivalence Discussion** |
|---|---|---|---|
| 3D-2D / 2D-2D Registration | AI module:<br>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).<br><br>Lower limbs module:<br>Panorama creation: Acquisition and save of fluoroscopy and angiography stage by stage keeping the same C-Arm orientation.<br><br>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. | AI module:<br>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).<br><br>PAD (lower limbs) module:<br>Panorama creation: Acquisition and save of fluoroscopy and angiography stage by stage keeping the same C-Arm orientation.<br><br>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 is updated manually. | Automatic motion detection<br>Registration: automatic/manual initialization and manual user validation. | **Different**<br>Improvement of semi-automatic registration (already existing requirement). The change does not significantly affect the use of the device. No new risks or possible errors were detected or identified. New clinical data were not necessary. V&V activities were performed and successful. No additional questions raised for safety and effectiveness. |
| Tools | AI module:<br>Draw markers on intra-operative images, locate/track points between per-op and pre-op images, and take measurements on pre-op CT scan images and fusion view.<br><br>Lower limbs module:<br>Draw lesions markers on panorama (stenosis and | AI module:<br>Draw markers on intra-operative images, locate/track points between per-op and pre-op images, and take measurements on pre-op CT scan images and fusion view.<br><br>PAD (lower limbs) module:<br>Draw lesions markers on panorama (stenosis and | Identical |

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| Medical Device Software Name | **EndoNaut (Predicate Device) K171829** | **EndoNaut (Subject Device)** | **Comparable Properties an Substantial Equivalence Discussion** |
|---|---|---|---|
| | thrombosis), calibrate the length of previous marked lesions due to inserted material, draw markers, create a control panorama. | thrombosis), calibrate the length of previous marked lesions due to inserted material, draw markers, create a control panorama. | |
| Patient contacting | No | No | Identical |
| Energy emitted or absorbed | No | No | Identical |
| Workstation main display & computer | Panel PC Baaske, model e-medic Silence TP 4<br><br>Rated AC 100-240V, 2.3-0.8A 50-60Hz<br><br>Monitor size: 24'' LCD<br>Brigthness: 250 cd/ m² typical<br>Resolution: 1920 x 1080<br>Cooling Fanless (no maintenance) | **Panel PC ACL OR-PC 27LP**<br><br>Rated AC 100-240V, **1.5-0.6 A ~47 – 63 Hz**<br><br>**Monitor size: 27'' LCD**<br>**Brightness: 300 cd/m2**<br><br>Resolution: 1920 x 1080<br>Cooling Fanless (no maintenance) | **Different**<br>No new risks or possible errors were detected or identified. V&V activities were performed and successful. No additional questions raised for safety and effectiveness. |
| Workstation secondary display (touch screen) | One Touch monitor ELO, model 1519LM,<br>rated AC 100-240V 1.2-0.63A 60/50Hz<br>Monitor size: 15.6'' LCD<br>Resolution: 1366 x 768<br>Brightness: 225 cd/m2<br>Touch technology: PCAP | One Touch monitor ELO model 1502L,<br>rated AC 100-240 V<br>Input frequency: 50-60 Hz<br>Monitor size: 15.6'' LCD<br>**Resolution: 1920 x 1080**<br>**Brightness: 270 cd/m2**<br>Touch technology: PCAP | Similar<br>**New monitor provides more effective visual image resolution.**<br>No new risks or possible errors were detected or identified. |
| 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. | Identical |
| Workstation dimensions | Height: 1742 mm<br>Width (footprint): 661 (640) mm<br>Depth (footprint): 950 (660) mm<br>Weight: 71 kg | **Height: 1740 mm**<br>Width (footprint): 661 (640) mm<br>Depth (footprint): 950 (660) mm<br>**Weight: 70 kg** | Similar<br>Minor dimensional and weight changes do not result in additional risks. |
| Connectors | Digital video input: DVI-D or DVI-I*<br>Analog video input: BNC<br>Video output: DisplayPort<br>Network:<br>10/100/1000 Mbps Ethernet (RJ45)<br>USB interface USB 3.0 (x2) | Digital video input: DVI-D or DVI-I*<br>**Video output: HDMI**<br>Network: 10/100/1000 Mbps Ethernet (RJ45)<br>USB interface USB 3.0 (x2) | Similar<br>Simply a new more common video interface is now used. |

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| Medical Device Software Name | **EndoNaut (Predicate Device) K171829** | **EndoNaut (Subject Device)** | **Comparable Properties an Substantial Equivalence Discussion** |
|---|---|---|---|
| Power supply | Input voltage:<br>100 – 230 VAC / 50 – 60 Hz | Input voltage:<br>100 – 230 VAC / 50 – 60 Hz | Identical |
| Workstation cablings | Connection Box<br>Front cable RJ45<br>DVI front cable<br>BNC front cable<br>USB 3.0 front cable 1m (x2)<br>Power supplies<br>Power supply extension jack 2.5mm 3m IEC extension cable 1m (red)<br>IEC extension cable 0.5m (blue)<br>External power supply ELO TOUCH 1519LM<br>External power supply Baaske<br>Video cabling: DVI 5m<br>Other cables:<br>DisplayPort DVI cable 1.5m<br>USB 3.0 A/B 1m<br>USB 2.0 2m | Connection Box<br>Front cable RJ45<br>DVI front cable<br>USB 3.0 front cable 1m (x2)<br><br>Power supplies<br>Power supply extension IEC C7-C14<br>Power supply extension jack 2.5mm 3m<br>IEC extension cable 1m (red)<br>IEC extension cable 0.5m (blue)<br>External power supply XP POWER (for ELO TOUCH 1502L)<br>External power supply BICKER (for ACL ORPC-27LP) BET-1012M<br>Video cabling: DVI 5m<br>Other cables:<br>HDMI cable 1.5m<br>HDMI/DP adapter<br>USB 3.0 A/B 1m<br>USB 2.0 2m<br>Equipotential 1,5m | **Different**<br><br>No new risks or possible errors were detected or identified. V&V activities were performed and successful. No additional questions raised for safety and effectiveness. |
| IEC 62304 | Applied | Applied | Identical |
| IEC 62366 | Applied | Applied | Identical |
| ISO 14971 | Applied | Applied | Identical |
| DICOM Standard parts 1-20 | Applied | Applied | Similar<br>A newer DICOM Conformance Statement has been written for EndoNaut System Software and is provided in Appendix 2. |
| Conformity to IEC 60601-1 of the separate interventional tools workstation | Yes<br>For CENELEC countries | Yes<br>For CENELEC countries | Identical<br>IEC 60601-1 is not a FDA recognized standard version but is applied and included in V&V protocol and results. |

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| Medical Device Software Name | **EndoNaut (Predicate Device) K171829** | **EndoNaut (Subject Device)** | **Comparable Properties an Substantial Equivalence Discussion** |
|---|---|---|---|
| Conformity to ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) of the separate interventional tools workstation | No | Yes | **Different**<br>US deviations to IEC 60601-1 are taken into account for the new model of separate interventional tools workstation (TS1CA2DS1-2). |
| Conformity to IEC 60601-2 of the separate interventional tools workstation | Yes | Yes | Identical<br>IEC 60601-2 FDA recognized standard version is applied and included in V&V protocol and results. |
| Conformity to IEC 60601-1-6 of the separate interventional tools workstation | Yes | Yes | Identical<br>IEC 60601-1-6 FDA recognized standard version is applied and included in V&V protocol and results. |

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## 6. Summary of the technical characteristics

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

EndoNaut (Subject Device) has similar HW and SW compatibilities, principle of operation and technical characteristics as the predicate device, EndoNaut.

EndoNaut workstation TS1CA2DS1-2 has similar material and technical characteristics (design, power, principle of operation) than the predicate accessory, the separate intervention tools workstation TS1CA2DS1-1.

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

## 7. Performance Data

The predicate device (K171829) 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
- Directions for use Reviews
- Testing on unit level (Module verification)
- Integration testing (EndoNaut Software embedded on the EndoNaut Workstation accessory and tests on several operating systems)
- Interoperability testing (with EndoSize Software)
- 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 as it its predicate TS1CA2DS1-1 by the COFRAC accredited testing laboratory. These tests showed that the EndoNaut Workstation TS1CA2DS1-2 meets the design specification and performed as intended.

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They 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
- IEC 62366 – medical devices – Application of usability engineering to medical devices

Specific to the 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

## 8. Statement of substantial equivalence

Based on the information supplied in this Special 510(k), Therenva SAS concludes that the EndoNaut (Subject device) and accessories

- are substantially equivalent to the predicate devices and accessories

and

- are safe and effective.