



Food and Drug Administration
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Therenva SAS
% Mr. Cemil Göksu
CEO
4 rue Jean Jaurès
Rennes 35000
FRANCE

April 12, 2016

Re: K160376
Trade/Device Name: EndoSize
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 26, 2016
Received: March 14, 2016

Dear Mr. 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. 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

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

Indications for Use

510(k) Number (if known)
K160376

Device Name
EndoSize

Indications for Use (Describe)

EndoSize enables visualization and measurement of structures of the heart and vessels for pre-operational planning and sizing for

cardiovascular interventions and surgery, and for postoperative evaluation.

General functionalities are provided such as:

- Segmentation of cardiovascular structures
- Automatic and manual centerline detection
- Visualization of CT scan images in every planes, 2D review, 3D reconstruction, Volume Rendering, MPR, Stretched CMPR
- Measurement and annotation tools
- Reporting tools

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SPECIAL 510(K) SUMMARY

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

Purpose: Therenva SAS hereby submits this special 510(k) (K160376) to provide a notification submission for proposed software changes in the already 510(k) cleared EndoSize software (K141475)

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Establishment Registration Number: 3011240766

Date prepared: 01/11/2016

Device Trade Name: EndoSize

Other Device Trade Names: Intelix

Device Common Name: Image processing software

Regulation Class Class II (21 CFR 892.2050, LLZ)

Classification Name: Picture Archiving Communications System

Identification of Predicate Device:

Device Classification Name	Picture Archiving Communications System
Regulation Number	892.2050
510(k) Number	K141475
Device Name	EndoSize
Product Code	LLZ
Decision	SUBSTANTIALLY EQUIVALENT (SE)

Device Description:

EndoSize is a stand-alone software application that runs on any standard Windows or Mac OSX based computer. It enables Physicians and Clinical Specialists to select patient CT scan studies from various data sources, view them, and process the images thanks to a comprehensive set of tools. EndoSize is intended to provide a clinical decision support system during the preoperative planning of endovascular surgery.

EndoSize contains five modules dedicated to different types of endovascular interventions, EndoSize EVAR, EndoSize FEVAR, EndoSize TEVAR, EndoSize TAVI and EndoSize Peripheral. These modules can be marketed in combination or as separate solutions. It is also possible to market custom versions of EndoSize to Stent manufacturers, based on the modules listed above. The differences between EndoSize and a custom version of EndoSize (user interface, manufacturer logo, manufacturer stent catalogue included in the software, optional features of a generic module), do not modify neither the functioning nor the safety of the software.

One custom version of EndoSize is marketed under the trademark "Intelix". This version includes the modules Intelix AFX and/or Intelix AFX2 and/or Intelix NELLIX which are customized versions of EndoSize EVAR module for specific endografts.

EndoSize enables assessment and measurement of different vascular structures such as vessels, valves, aneurysms, and other anomalies. It provides simple techniques to assess the feasibility of endovascular procedures. EndoSize can combine 2D scan slices into comprehensive 3D models of the patient, and can display supporting DICOM CT scan data. The software accurately represents different types of tissue, making it easier to diagnose anomalies in scans. It works with DICOM CT scan images and can access multiple DICOM data files and PACS server.

Intended Use:

EndoSize is a software solution that is intended to provide Physicians and Clinical Specialists with additional information to assist them in reading and interpreting DICOM CT scan images of structures of the heart and vessels.

EndoSize enables the user to visualize and measure (diameters, lengths, volumes, angles) structures of the heart and vessels.

Indications for Use:

EndoSize enables visualization and measurement of structures of the heart and vessels for pre-operational planning and sizing for cardiovascular interventions and surgery, and for postoperative evaluation.

General functionalities are provided such as:

- Segmentation of cardiovascular structures
- Automatic and manual centerline detection
- Visualization of CT scan images in every planes, 2D review, 3D reconstruction, Volume Rendering, MPR, Stretched CMPR
- Measurement and annotation tools
- Reporting tools

Technological Characteristics:

EndoSize is a software-only device that runs on a standard computer that meets the minimum requirements. It can use local DICOM files or distant PACS server. The device does not contact the patient, nor does it control any life sustaining devices. The information and measurements displayed, exported or printed are validated and interpreted by Physicians.

EndoSize complies with the DICOM voluntary standards (ACR/NEMA Digital Imaging and Communication in Medicine).

Performance Data:

The subject device is designed in conformance with:

- ACR/NEMA Digital Imaging Communication in Medicine (DICOM) Version 3.1
- ISO 14971:2012 – Medical devices – Application of risk management to medical devices
- IEC 62304:2006 – Medical device software – Software life-cycle processes

Every specification of the EndoSize software is validated by a bench test before release. Bench testing includes:

- Tests of Importation of DICOM images
- Patient Manager tests
- Tests of image display and processing
- Functioning tests of the different modules EVAR, TEVAR, FEVAR, TAVI, Peripheral, Intelix AFX, Intelix AFX2 and Intelix NELLIX
- Measurement tests
- Reports creation and exportation tests

Every modification to the EndoSize software is validated by the same bench testing as described above.

After modification to the EndoSize software, a regression testing, consisting of the testing of all specifications of the software as described above, is performed.

Design changes

THERENVA is updating some components and adding new features based on the existing software technology, to enhance performance and user experience of EndoSize. The fundamental scientific technology of the modified device has not changed, nor have the indications for use.

Device Modifications	Rationale for Changes
Catalogue update: inclusion of the latest endograft references	Improved existing functionality
New warnings and disclaimers related to user validation of measurements, key points placement and health care provider's responsibility	Improved performance and user experience
PATIENT MANAGER COMPONENT	
Patient Manager new minor functionalities: choose default database, reset sizing data	Improved user experience
SHARED FUNCTIONS (ALL MODULES)	
MPR view new minor functionalities: new shortcuts, full screen view, synchronized zoom, new toolbar	Improved user experience
MIP rendering on MPR view	Improved performance and user

	experience
The user can import external images to the sizing report	Improved user experience
The user can organize snapshots in the sizing report	Improved user experience
Calcium estimation tool: The user can measure calcification volume in a region of interest (ROI). The user chooses the ROI and the Hounsfield Unit (HU) thresholds for the measure. The function is based on the volume measurement technology already existing in the predicate device.	Improved performance
C-arm angle tool: The user can move the 3D view and visualize and record the corresponding C-arm angles (LAO/RAO and cranial/caudal). In the previous version of EndoSize (predicate) the C-arm angle values were already displayed in the 3D view, but this tool is now considered as a “custom measure” that can be recorded in the measurement panel and in the sizing report.	Improved performance
PERIPHERAL MODULE	
NASCET value calculation	Improved performance
INTELIX MODULES (AFX, AFX2 and NELLIX MODULES)	
New warnings and disclaimers related to virtual rendering of device components, polymer volume estimation, and health care provider’s responsibility	Improved performance and user experience
Custom IFU: the user can access pdf versions of specific IFUs dedicated to Intelix AFX, Intelix AFX2 and Intelix NELLIX modules, in addition to the General User Manual	Improved performance and user experience
Custom measurements step: Additional key measurements proposed in the “measurements panel” for better sizing of AFX / AFX2 / NELLIX endografts.	Improved user experience
Custom planning strategy and sizing sheet: <ul style="list-style-type: none"> - Modified sizing sheet with additional key measurements for INTELIX modules - AFX / AFX2 / NELLIX endograft catalogs only 	Improved user experience
Custom sizing report: <ul style="list-style-type: none"> - AFX / AFX2 / NELLIX logo - Modified sizing sheet - 3D view snapshot of the aneurysm added to the report by default 	Improved user experience
The user can create and manage assemblies of components and visualize a 3D view of selected devices	Improved user experience
The user can send emails with the pdf sizing report attached from the software through its email client	Improved user experience

Predicate Device Comparison:

EndoSize has same intended use and fundamental scientific technology of the legally marketed device. The differences between the devices do not raise any questions with respect to the safety and effectiveness of the subject device.

Legally Marketed Device	Modified Subject Device
<p style="text-align: center;">EndoSize version 3.0</p> <p style="text-align: center;">Therenva</p> <p style="text-align: center;">K141475</p> <p style="text-align: center;">(Predicate Device)</p>	<p style="text-align: center;">EndoSize version 3.1</p> <p style="text-align: center;">Therenva</p> <p style="text-align: center;">K160376</p>
<p>EndoSize is a software solution that is intended to provide Physicians and Clinical Specialists with additional information to assist them in reading and interpreting DICOM CT scan images of structures of the heart and vessels.</p> <p>EndoSize enables the user to visualize and measure (diameters, lengths, volumes, angles) structures of the heart and vessels.</p> <p><u>Indications for Use:</u></p> <p>EndoSize enables visualization and measurement of structures of the heart and vessels for pre-operational planning and sizing for cardiovascular interventions and surgery, and for postoperative evaluation.</p> <p>General functionalities are provided such as:</p> <ul style="list-style-type: none"> • Segmentation of cardiovascular structures • Automatic and manual centerline detection • Visualization of CT scan images in every planes, 2D review, 3D reconstruction, Volume Rendering, MPR, Stretched CMPR • Measurement and annotation tools • Reporting tools 	<p>EndoSize is a software solution that is intended to provide Physicians and Clinical Specialists with additional information to assist them in reading and interpreting DICOM CT scan images of structures of the heart and vessels.</p> <p>EndoSize enables the user to visualize and measure (diameters, lengths, volumes, angles) structures of the heart and vessels.</p> <p><u>Indications for Use:</u></p> <p>EndoSize enables visualization and measurement of structures of the heart and vessels for pre-operational planning and sizing for cardiovascular interventions and surgery, and for postoperative evaluation.</p> <p>General functionalities are provided such as:</p> <ul style="list-style-type: none"> • Segmentation of cardiovascular structures • Automatic and manual centerline detection • Visualization of CT scan images in every planes, 2D review, 3D reconstruction, Volume Rendering, MPR, Stretched CMPR • Measurement and annotation tools • Reporting tools
<p><u>Interface to image sources:</u> DICOM image data</p>	<p><u>Interface to image sources:</u> DICOM image data</p>
<p><u>Import of Patient Data:</u> Manual through keyboard/mouse Automatic import with image file Study List Creation</p>	<p><u>Import of Patient Data:</u> Manual through keyboard/mouse Automatic import with image file Study List Creation</p>
<p><u>Study list image functionality:</u> Exporting Deleting Anonymizing Search</p>	<p><u>Study list image functionality:</u> Exporting Deleting Anonymizing Search Choose a default database Reset sizing</p>
<p><u>Image Processing:</u></p>	<p><u>Image Processing:</u></p>

<p>Realign orthogonal MPRs Segmentation toolset: Automatic segmentation Automatic centerline Manual centerline Centerline editing Undo/redo operations Volume sculpting</p>	<p>Realign orthogonal MPRs Segmentation toolset: Automatic segmentation Automatic centerline Manual centerline Centerline editing Undo/redo operations Volume sculpting</p>
<p><u>Image assessment:</u> Linear (length and diameter) and angular measurements Volume measurements C-Arm angulation calculation</p> <p>Test annotations on snapshots Calcium scoring for assessment of calcium in the aortic root</p>	<p><u>Image assessment:</u> Linear (length and diameter) and angular measurements Volume measurements C-Arm angulation calculation and record in the sizing report Test annotations on snapshots Calcium scoring for assessment of calcium in the aortic root Calcium volume measurement NASCET calculation in Peripheral module</p>
<p><u>Image display:</u> Orthogonal, oblique, double oblique, curved, cross-curved MPR rendering</p> <p>MIP volume rendering</p> <p>Color volume rendering 2D slice review Endoscopic view Interactive VOI clipping Multi-tissue color and opacity control Active presets User-defined presets</p>	<p><u>Image display:</u> Orthogonal, oblique, double oblique, curved, cross-curved MPR rendering (with new shortcuts and full screen view available) MIP volume rendering (available in MPR view for every module) Color volume rendering 2D slice review Endoscopic view Interactive VOI clipping Multi-tissue color and opacity control Active presets User-defined presets 3D view of assemblies of devices</p>
<p><u>DICOM Support:</u> Compatible with all scanner vendor DICOM datasets Storage SCP Import DICOM files DICOM compliance for CT and enhanced CT Import from DICOMDIR Storage SCU Query/retrieve SCU</p>	<p><u>DICOM Support:</u> Compatible with all scanner vendor DICOM datasets Storage SCP Import DICOM files DICOM compliance for CT and enhanced CT Import from DICOMDIR Storage SCU Query/retrieve SCU</p>
<p>Storage of Results Printout Session state PDF format</p>	<p>Storage of Results Printout Session state PDF format Send report by email Import external image to the sizing report Up-to-date catalogues</p>
<p>MS Windows Mac OSX</p>	<p>MS Windows Mac OSX</p>

Conclusion

The modified EndoSize software is substantially equivalent to the legally marketed device (predicate device) in terms of intended use, indications for use and technical characteristics. The modified EndoSize software has successfully undergone bench testing.

Based on the information supplied in this special 510(k), THERENVA SAS concludes that the new version of EndoSize is substantially equivalent to the predicate device, is safe and effective and performs as well or better than the predicate device.