JUL 3 1 2014

K141475
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510(K) SUMMARY (21 CFR 807.92(C))

Manufacturer Name:	Therenva SAS Centre d'Innovation Technologique Niv. 0 du CCP 2 rue Henri Le Guilloux 35000 Rennes FRANCE
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Official Correspondant :	
Establishment Registration Number:	Awaiting acceptance of this 510k
Date prepared:	12/19/2013
Trade Name:	EndoSize
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	K120367
Device Name	3mensio Workstation
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 which meets the minimal requirements. 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, EVAR, FEVAR, TEVAR, TAVI and 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 catalogue included in the software, optional features of a generic module) do not modify neither the functioning nor the safety of the software.

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 and plan interventional procedures. 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 and Peripheral
- Measurement tests
- Reports creation and exportation tests

Predicate Device Comparison:

EndoSize has similar intended use and technical features of the predicate device listed above. The differences between the devices do not raise any questions with respect to the safety and effectiveness of the subject device.

New Device	Predicate Device
EndoSize Therenva	3mensio Workstation Pie Medical Imaging K120367
Interface to image sources: DICOM image data	Interface to image sources: DICOM image data
Import of Patient Data: Manual through keyboard/mouse Automatic import with image file Study List Creation	Import of Patient Data: Manual through keyboard/mouse Automatic import with image file Study List Creation
Study list image functionality: Exporting Deleting Anonymizing Search	Study list image functionality: Exporting Deleting Anonymizing Search
Image Processing: Realign orthogonal MPRs Segmentation toolset: Automatic segmentation Automatic centerline Manual centerline Centerline editing Undo/redo operations Volume sculpting	Image Processing: Realign orthogonal MPRs Segmentation toolset: Automatic segmentation Automatic centerline Manual centerline Centerline editing Undo/redo operations Volume sculpting
Image assessment: Linear (length and diameter) and angular measurements Volume measurements C-Arm angulation calculation Test annotations on snapshots Calcium scoring for assessment of calcium in the aortic root	Image assessment: Linear (length and diameter), angular and ROI measurements Volume measurements C-Arm angulation calculation Text and arrow annotations Calcium scoring for assessment of calcium in the aortic root
Image display: Orthogonal, oblique, double oblique, curved, cross-curved, stretched MPR rendering MIP volume rendering Color volume rendering	Image display: Orthogonal, oblique, double oblique, curved, cross-curved, stretched MPR rendering MIP, AveIP, MinIP and color volume slabs MIP volume rendering

2D slice review Endoscopic view Interactive VOI clipping Multi-tissue color and opacity control Active presets User-defined presets	Color volume rendering Greyscale volume rendering 2D slice review and stack comparison 4D cine Interactive VOI clipping Multi-tissue color and opacity control Active presets User-defined presets
DICOM Support: 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	DICOM Support: Compatible with all scanner vendor DICOM datasets Storage SCP Import DICOM files DICOM compliance for CT, enhanced CT, MRI, enhanced MRI, XA, Nuclear Medicine, CR, SC, and Ultrasound images Import from DICOMDIR Storage SCU Query/retrieve SCU Automatic grouping of images into volumes Windows printing or send to PACS
Storage of Results Printout Session state PDF format	Storage of Results Printout Session state PDF format DICOM PDF report
MS Windows Mac OSX	MS Windows

Conclusion

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 31, 2014

Therenva SAS
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K141475
Trade/Device Name: EndoSize
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 1, 2014
Received: July 2, 2014

Dear Mr. Job:

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,

for

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141475

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.
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- 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 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*