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

June 23, 2017

EBIT S.r.l
% Ms. Allison Scott
Associate Director
Navigant Consulting, Inc.
9001 Wesleyan Road, Suite 200
INDIANAPOLIS IN 46268

Re: K163668
Trade/Device Name: SUITESTENSA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 31, 2017
Received: June 1, 2017

Dear Ms. Scott:

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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163668

Device Name
SUITESTENSA

Indications for Use *(Describe)*

SUITESTENSA is an integrated software system for the management and reporting of diagnostic-instrumental procedures in Cardiology and Radiology departments. It is intended to support and assist trained professionals in the diagnostic process, through the acquisition, storage, viewing, processing and reporting of cardiology and radiology imaging studies and ECG traces. SUITESTENSA also allows transfer of images to CD/DVD.

SUITESTENSA may be used also for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM For Presentation format and displayed on FDA cleared, DICOM compatible displays for mammography.

SUITESTENSA is intended to be used by qualified professionals, i.e. doctors (radiologists, cardiologists, etc.), ward technicians, paramedics, administrative personnel, specialist ward doctors.

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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510(k) Summary

I. SUBMITTER

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Contact Person: Marco Fruscione
Date Prepared: December 22, 2016

II. DEVICE

Name of Device:	SUITESTENSA
Common or Usual Name:	Picture Archiving Communication System
Classification Name:	Picture Archiving Communication System (21 CFR 892.2050)
Regulatory Class:	II
Product Code:	LLZ

III. PREDICATE DEVICE

Tradename	Class	Product Code	Manufacturer	K Number
PRIMARY PREDICATE - This predicate has not been subject to a design-related recall.				
Synapse PACS 5.1.0	II	LLZ	FUJIFILM Medical Systems U.S.A., Inc.	K160108
REFERENCE PREDICATES				
Synapse MPR/Fusion Software	II	LLZ	FUJIFILM Medical Systems U.S.A., Inc.	K113244
McKesson Cardiology	II	LLZ	McKesson Technologies, Inc.	K151850

IV. DEVICE DESCRIPTION

SUITESTENSA Software is a RIS/CIS/PACS software suite managing the entire clinical workflow of a Radiology and Cardiology Department through the following software modules being part of the Software Suite:

- SUITESTENSA PACS – Archiving Software System
- SUITESTENSA Review – Diagnostic Reporting Software
- SUITESTENSA RIS – Radiology Information System
- SUITESTENSA CIS – Cardiology Information System
- SUITESTENSA MPS – Media Production Software System
- SUITESTENSA QC – Integration Process Quality Control

SUITESTENSA natively integrates SUITESTENSA RIS/CIS and may integrate with any other third party RIS/CIS software that has HL7 interface capabilities.

Module	**Functionalities**
SUITESTENSA PACS	Images acquisition from diagnostic modalities Images archiving with hierarchical archive management software Images retrieval and distribution to diagnostic reporting workstation
SUITESTENSA Review	Diagnostic multi-modalities reporting viewing software
SUITESTENSA RIS	Complete exam workflow management in a Radiology/Nucleare Medicine Department including: -exam scheduling, acceptance, execution, reporting
SUITESTENSA CIS	Complete exam workflow management in a Cardiology Department including: -exam scheduling, acceptance, execution, reporting
SUITESTENSA Media Production System	Publishing of CD/DVDs used to provide visual documentation to supply to the patient and healthcare specialists, replacing the need to print out the conventional X-ray, image or ECG traces
SUITESTENSA Quality Control	Module to manage the complete integration process between the RIS/CIS modules and the PACS module

V. INDICATIONS FOR USE

SUITESTENSA is an integrated software system for the management and reporting of diagnostic-instrumental procedures in Cardiology and Radiology departments. It is intended to support and assist trained professionals in the diagnostic process, through the acquisition, storage, viewing, processing and reporting of cardiology and radiology imaging studies and ECG traces. SUITESTENSA also allows transfer of images to CD/DVD.

SUITESTENSA may be used also for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM For Presentation format and displayed on FDA cleared, DICOM compatible displays for mammography.

SUITESTENSA is intended to be used by qualified professionals, i.e. doctors (radiologists, cardiologists, etc.), ward technicians, paramedics, administrative personnel, specialist ward doctors.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

SUITESTENSA is a software suite consisting of different modules that allows a user to customize suite capabilities to their particular needs. SUITESTENSA is used for acquisition, storage and viewing of cardiology and radiology images with additional capabilities for workflow management, transfer to CD/DVD, and image distribution to a diagnostic workstation.

SUITESTENSA is substantially equivalent to the FUJIFILM Synapse PACS 5.1.0 system, since both are used for acquisition, storage, viewing and processing of diagnostic images with additional capabilities for workflow management, transfer to CD/DVD, and image distribution to a diagnostic workstation.

Both the devices offer intended uses for soft-copy image diagnostic reporting as they can be configured with one or more of the following application:

<u>Radiology Application</u>

- Basic X-Ray, CT. MR, US Reporting
- Mammography Reporting
- MR/CT 3D Post Processing
- Vascular Analysis

<u>Cardiology Application</u>

- Cathlab Image Reporting
- Echo Cardiology Image Reporting
- ECG Waveform Reporting

General Application

With a focus on safe image management for diagnostic reporting, the devices are used for the following general application, not directly used in the clinical practice, but necessary for the diagnostic clinical practice:

- Reliable and Safe Data Archiving
- Integration process between the RIS/CIS modules and the PACS module

At a high level the subject and predicate devices are based on the following same technological and functional elements:

- Images and data communication in both the devices are in compliance with the HL7 and DICOM Standard as well the integration workflow.
- O/S Technology Platform Server are Windows Based.
- Both devices support ORACLE DB Engine and support advanced high level storage system that guarantee business continuity and data recovery
- Client application may be run over Internet Browser User Interface in order to guarantee broader access
- A set of basic and advanced image display and processing function are available such as

Decompression for compressed images before display
Display images
Viewing Reports
Hanging Protocol
Spine Labeling
Reference line display
Key images identification
Link multiple series
Measurement Tools
Annotation Tools
Standard Image Manipulation Tools (Window width/level, Zoom, Pan, etc.)
Display of Digital Mammography Images
Orthogonal and Oblique Multi Planar Reconstruction (MPR)
Maximum, Average, and Minimum Intensity Projection (MIP, MPVR, MinIP)
Curved Multi Planar Reconstruction (CPR)
Save Preferences by User Profile
Save Window/Level Preferences

The following technological differences exist between the subject and predicate devices:

- The client platform for the predicate devices is platform independent while the subject devices supports also Desktop Client for the Cardiology Domain
- Use of a different DB Engine Option (MS SQL is not supported by the predicate device)
- Support in the Multi-Modal Fusion Image Processing
- Support for analysis and quantification of cardiovascular digital images (not available in the predicate devices but in a reference device)

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination. The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could indirectly result in minor injury to the patient through incorrect or delayed information or through the action of the care provider.

Software Verification and Validation Testing
Software verification and validation testing was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and in accordance with ISO 62304, Medical Device Software – Software Lifecycle Process.

Software verification and validation was performed to ensure it met all the specification requirements and conformance testing.

VIII. CONCLUSIONS

Based on the results of the software verification testing and the proposed Indications for Use, the SUITESTENSA software is considered substantially equivalent to the FUJIFILM Synapse PACS 5.1.0 system.