



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

Visible Patient, SAS
% John Smith, M.D., Ph.D.
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth Street, NW
WASHINGTON DC 20004

October 15, 2015

Re: K151988
Trade/Device Name: Visible Patient Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 9, 2015
Received: September 9, 2015

Dear Dr. Smith:

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 black ink that reads "Robert Ochs". The signature is written in a cursive style with a light grey shadow effect behind the text.

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)

K151988

Device Name

Visible Patient Suite

Indications for Use (Describe)

Visible Patient Suite is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Visible Patient Suite accepts DICOM compliant medical images acquired from a variety of imaging devices, including CT, MR.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

The software provides several categories of tools. It includes basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal Multi-Planar Reconstructions (MPR), image fusion, surface rendering, measurements, reporting, storing, general image management and administration tools, etc.

It includes a basic image processing workflow and a custom UI to segment anatomical structures, which are visible in the image data (bones, organs, vascular/airway structures, etc.), including interactive segmentation tools, basic image filters, etc.

It also includes detection and labeling tools of organ segments (liver, lungs and kidneys), including path definition through vascular/airway, approximation of vascular/airway territories from tubular structures and interactive labeling.

The software is designed to be used by trained professionals (including physicians, surgeons and technicians) and is intended to assist the clinician who is solely responsible for making all final patient management decisions.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."

510(k) SUMMARY
Visible Patient, SAS's Visible Patient Suite

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Visible Patient, SAS
RCS Strasbourg TI 794 458 125
1 place de l'hôpital
67000 Strasbourg, France
Phone: 33 (0)3 90 22 42 00
Facsimile: 33 (0)3 88 11 90 99

Contact Person: Ms. Aude PETITJEAN
Phone number: 33 (0)3 90 22 42 03

Date Prepared: July 17, 2015

Name of Device and Name/Address of Sponsor

Visible Patient Suite
Visible Patient, SAS
RCS Strasbourg TI 794 458 125
1 place de l'hôpital
67000 Strasbourg, France

Common or Usual Name

Medical Image Processing Software

Classification Name / Regulation Number / Product Code / Review Panel

Picture Archiving and Communications System / 21 C.F.R. § 892.2050 / Product Code: LLZ /
Radiology Review Panel

Predicate Devices

- FUJIFILM Medical Systems U.S.A., Inc.'s:
- Synapse 3D Base Tools (K120361)
 - Synapse 3D Liver and Kidney Analysis (K142521)
 - Synapse 3D Lung and Abdomen Analysis (K130542)

Intended Use / Indications for Use

Visible Patient Suite is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Visible Patient Suite accepts DICOM compliant medical images acquired from a variety of imaging devices, including CT, MR.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

The software provides several categories of tools. It includes basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal Multi-Planar Reconstructions (MPR), image fusion, surface rendering, measurements, reporting, storing, general image management and administration tools, etc.

It includes a basic image processing workflow and a custom UI to segment anatomical structures, which are visible in the image data (bones, organs, vascular/airway structures, etc.), including interactive segmentation tools, basic image filters, etc.

It also includes detection and labeling tools of organ segments (liver, lungs and kidneys), including path definition through vascular/airway, approximation of vascular/airway territories from tubular structures and interactive labeling.

The software is designed to be used by trained professionals (including physicians, surgeons and technicians) and is intended to assist the clinician who is solely responsible for making all final patient management decisions.

Technological Characteristics

The Visible Patient Suite is a software device that does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the software, but by radiologists, clinicians and referring physicians. A physician, provided with ample opportunity for competent human intervention, interprets images and information being displayed.

In sum, Visible Patient Suite is a software suite and includes three software components: Visible Patient Sender (VP Sender), Visible Patient Lab (VP Lab), and Visible Patient Planning (VP Planning). Visible Patient Lab is the main software component of Visible Patient Suite and includes all modules available in the software suite (except for the DICOM files anonymization module present in the Visible Patient Sender module).

a) Visible Patient Sender

Visible Patient Sender includes only modules dedicated to data management. The software is a simple tool to anonymize multidimensional digital images acquired from a variety of medical imaging modalities (DICOM images). There is no 3D data volume interpretation in this software.

b) Visible Patient Lab

Visible Patient Lab includes all Visible Patient Suite modules: data management (except for DICOM files anonymization module), data analysis and data processing. This software offers a flexible solution to help trained medical professionals with image processing knowledge (usually radiologists or radiologist technicians) in (1) the evaluation of patient's anatomy and pathology, and (2) in the creation of a 3D model of the patient's anatomy. This software proposes flexible workflow options: visualization of patient's anatomy and pathology from medical images; creation a 3D model of the patient's anatomical structures, organ segments and volumetric data; creation of an anatomical atlas (a colored image where each color represents a structure); and exports these medical data to be analyzed or reviewed later.

c) Visible Patient Planning

Visible Patient Planning includes modules dedicated to data management and data analysis, and simply contains a subset of the software modules present in Visible Patient Lab. This software offers a flexible visualization solution to help trained medical professionals (clinicians) in the evaluation of patient's anatomy and pathology to plan therapy or surgery.

Performance Data

The company has verified and validated the Visible Patient Suite's moderate level of concern software. In all instances, the Visible Patient Suite functioned as intended.

Substantial Equivalence

The Visible Patient Suite is as safe and effective as the Synapse 3D Base Tools (K120361), Synapse 3D Liver and Kidney Analysis (K142521) and Synapse 3D Lung and Abdomen Analysis (K130542). The Visible Patient Suite has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Visible Patient Suite and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Visible Patient Suite performs as intended and in a manner similar to the predicate devices. Thus, the Visible Patient Suite is substantially equivalent.