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

November 5, 2021

Re: K212896
Trade/Device Name: Visible Patient Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 10, 2021
Received: September 10, 2021

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. 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 and Part 809); 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,

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)*

K212896

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 for both pediatric and adult patients. 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)*

X 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

Visible Patient SAS's Visible Patient Suite

K212896

Submitter

Visible Patient, SAS
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Phone: +33 (0)3 68 66 81 81

Contact Person: Ms. Emeline DEGIVRY

Date Prepared: October 29, 2021

Name of Device: Visible Patient Suite

Common or Usual Name: Medical Image Processing Software

Classification Name: Medical Image Management and Processing System

Regulatory Class: Class II

Regulation number: 892.2050

Product Code: LLZ

Predicate Device

Visible Patient Suite, Visible Patient, SAS, K151988

Indications For Use

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Technological Characteristics

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.

The technological characteristics are the same between the present Visible Patient Suite and the predicate. Minor incremental updates were made to the subject device, however, these differences do not raise different questions of safety and effectiveness.

Performance Data

The company has verified and validated the Visible Patient Suite's moderate level concern software.

All functionalities were tested during the test phase of the development. Each feature can be used for pediatric or adult patients. For the volume computation and distance measurement, all tests were performed on phantom data with pre-established physical characteristics (specific measures and volumes).

During the validation stage, a literature study was conducted to support device performance.

Conclusions

The subject Visible Patient Suite is as safe and effective as the predicate Visible Patient Suite device (K151988).

The Indications for use only differ by the clarification of the patient population (pediatric and adult population). This difference does not alter the Intended use of the device.

The Visible Patient Suite has the same technological characteristics, and principles of operation as its predicate device. 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 to the predicate.