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

Visage Imaging GmbH
% Mr. Stefan Strowich
Manager of Quality Systems and Regulatory Affairs
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GERMANY

April 28, 2015

Re: K142196
Trade/Device Name: Visage Ease Pro
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 11, 2015
Received: February 12, 2015

Dear Mr. Strowich:

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K142196

Device Name
Visage Ease Pro

Indications for Use *(Describe)*

Visage Ease Pro is a mobile client for diagnostic image viewing of radiological images from the following modalities: X-ray, CT, MRI, PET, SPECT, Ultrasound and XA. It is based on the Visage 7 product for distributing, viewing, processing, and archiving medical images within and outside health care environments.

Visage Ease Pro must only be used by trained health care professionals. It may support physicians and/or the medical staff by providing mobile access to relevant medical images. Any diagnostic or therapeutic decision resides with the doctors and/or the medical staff in their respective area of responsibility.

Visage Ease Pro is not intended to replace full radiologic reading workstations. It must not be used in the context of diagnostic or therapeutic decisions if a radiologic reading workstation with appropriate display hardware is available. The user must make sure that the reading environment complies with any applicable diagnostic requirements and the state-of-the-art.

Visage Ease Pro must not be used for primary image diagnosis in mammography or digital breast tomosynthesis.

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 of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, Visage Imaging GmbH herewith submits a Summary of Safety and Effectiveness.
This 510(k) summary for the Visage Ease Pro meets the requirements of 21 CFR 807.92.

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Date Prepared: August 04st, 2014

Visage Imaging GmbH
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Device(s) Identification:

Device Trade Name:	Visage Ease Pro
Release Version:	1.5
Device Classification Name:	System, Image Processing, Radiological
Regulation Description:	Picture archiving and communications system
Product Code:	LLZ
Reference:	per 21 CFR 892.2050
Review Panel:	Radiology
Device Class:	II

Device Description:

Visage Ease Pro is a mobile client for diagnostic image viewing of radiological images, image review by clinicians and image display for illustration and educational purposes. It is based on the Visage 7 product for distributing, viewing, processing, and archiving medical images within and outside health care environments.

Visage Ease Pro has a graphical user interface which is optimized for mobile devices with a touch screen. The app allows searching for studies and viewing images and reports. The user may zoom and pan images, adjust the window level, browse through a stack of images or play a cine animation. Patient and image information is displayed as viewer text. The app supports voice memos, image attachments and push notifications.

Visage Ease Pro is designed as a thin client in a single module and allows to remotely access the images on a Visage 7 server. The communication between the mobile client and the server is encrypted. The user must authenticate himself with username and password. A connection can only be established, if the user has the appropriate permissions for using the mobile client. These permissions are configurable on the Visage 7 server.

Intended Use:

Visage Ease Pro is a mobile client for diagnostic image viewing of radiological images, image review by clinicians and image display for illustration and educational purposes. It is based on the Visage 7 product for distributing, viewing, processing, and archiving medical images within and outside health care environments (cf. Intended Use – Visage 7 [1]).

Visage Ease Pro must only be used by trained health care professionals. It may support physicians and/or the medical staff by providing mobile access to relevant medical images. Any diagnostic or therapeutic decision resides with the doctors and/or the medical staff in their respective area of responsibility.

Visage Ease Pro must not be used in the context of diagnostic or therapeutic decisions if a radiologic reading workstation with appropriate display hardware is available. The user must make sure that the reading environment complies with any applicable diagnostic requirements and the state-of-the-art.

Visage Ease Pro must not be used for primary image diagnosis in mammography.

Predicate devices:

1.
Device Trade Name: Visage PACS 6.0 / CS 3.1 (Visage 7)
Applicant: Visage Imaging, INC.
510(k) No.: K082269

2.
Device Trade Name: Mobile MIM (RT)
Applicant: MIM Software Inc.
510(k) No.: K112930

The Visage Ease Pro is considered substantial equivalent to the Visage PACS 6.0 / CS 3.1 (K082269), Mobile MIM (RT) (K112930).
Intended use, medical application and treatment method as well as the basic parameter settings are equivalent for the Visage Ease Pro, the Visage PACS 6.0 / CS 3.1 and the Mobile MIM (RT).

Summary of Technological Characteristics

The relevant clinical functions and technological characteristics of Visage Ease Pro are also included in the Mobile MIM (RT) software. The typical work flow is very similar for both devices. Both software devices show an identical behavior and would lead to the same diagnosis. Visage Ease Pro did not have any additional clinical functionality in comparison to Visage 7.

Summary of testing:

Visage Ease Pro is clinically validated against predicate devices. The clinical validation focuses on primary operating functions for clinical use cases. Visage Ease Pro is clinically validated against the predicate devices Visage 7® and Mobile MIM™.
The primary operating functions covered by the clinical validation are loading of images, selecting a series of images, adjusting the window level, zooming and panning an image, browsing through a stack of images, and playing cine animations.
The data sets for the modalities CT, CR, DX, MRI, PET, SPECT, US, and XA are viewed with the predicate devices and Visage Ease Pro.

Conclusion:

Visage Imaging GmbH believes that the Visage Ease Pro is substantially equivalent to the currently legally marketed devices. The Visage Ease Pro does not introduce new indications for use, have the same technological characteristics and does not introduce new potential hazards or safety risks.