Visage Imaging GmbH   January 29, 3021
℅ Juliane Dinter
Lead Project Manager
QiP GmbH
Struveweg 40
LUDWIGSFELDE, BRANDENBURG 14974
GERMANY

Re: K201411
    Trade/Device Name: Visage Breast Density
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Picture Archiving And Communications System
    Regulatory Class: Class II
    Product Code: QIH
    Dated: December 21, 2020
    Received: December 23, 2020

Dear Juliane Dinter:

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); 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
Division 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: 06/30/2020

See PRA Statement below.

510(k) Number *(if known)*
K201411

Device Name
Visage Breast Density

Indications for Use *(Describe)*
Visage Breast Density is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. Visage Breast Density assesses breast density from a mammography study and provides an ACR BI-RADS Atlas 5th Edition breast density category to aid radiologists in the assessment of breast tissue composition. Visage Breast Density produces adjunctive information. It is not a diagnostic aid.

Visage Breast Density is based on the Visage 7 product for distributing, viewing, processing, and archiving medical images.

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.

Traditional 510(k) Summary

Visage Breast Density

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92.

Submitter

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Contact Person	Stefan Strowich Manager of Quality Systems and Regulatory Affairs
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Phone Number	+49 30 700968-41
Date Prepared	January 28, 2021

Device

Trade Name	Visage Breast Density
Common Name	Medical Imaging Software
Classification Name	Automated Radiological Image Processing Software
Regulatory Number	21 CFR 892.2050
Product Code	QIH
Device Class	Class II
Review Panel	Radiology

Predicate Device

Trade Name	PowerLook Density Assessment
Common Name	Medical Imaging Software
Classification Name	System, Image Processing, Radiology
Regulatory Number	21 CFR 892.2050
Product Code	LLZ
Device Class	Class II
Review Panel	Radiology
Submitter	iCAD, Inc.
510(k) Number	K180125
Clearance	April 5, 2018

Device Description

Visage Breast Density is a software application that assesses breast density from a mammography study and provides a density category A, B, C, or D according to the ACR BI-RADS Atlas 5th Edition to aid radiologists in the assessment of breast tissue composition.

Visage Breast Density employs a convolutional neural network (CNN) for the automatic classification of breast density. The CNN has been trained on a large database of mammography exams. When applied to a mammography image, the CNN computes four likelihoods corresponding to the four breast density categories. The classifications of the individual images are merged into a general classification of the mammography study.

Visage Breast Density is designed as an add-on module to the Visage 7[1] product for distributing, viewing, processing, and archiving medical images. The assessment of breast density is performed from mammography studies stored on the Visage 7 server. The resulting breast density classification is displayed by the Visage 7 client on a computer monitor and stored in the database on the Visage 7 server.

Indications for Use

Visage Breast Density is a software application intended for use with compatible full field digital mammography and digital breast tomosynthesis systems. Visage Breast Density assesses breast density from a mammography study and provides an ACR BI-RADS Atlas 5th Edition breast density category to aid radiologists in the assessment of breast tissue composition. Visage Breast Density produces adjunctive information. It is not a diagnostic aid.

Visage Breast Density is based on the Visage 7 product for distributing, viewing, processing, and archiving medical images.

Comparison with Predicate Device

The technical characteristics of Visage Breast Density and the predicate device PowerLook Density Assessment are comparable.

The devices under comparison are software applications that assess breast density and provide a density category according to the ACR BI-RADS Atlas 5th Edition. Both devices are intended as an interpretative aid in the assessment of breast tissue composition. They have the same product classification, same level of concern, same patient population and similar intended users.

Visage Breast Density uses a trained convolutional neural network with digital mammography images. The predicate device determines the density category of tomosynthesis 2D synthetic images based on a calculation of area covered by dense tissue. Despite the different analysis techniques, non-clinical testing showed that Visage Breast Density achieves similar accuracies compared to the predicate device.

Both applications are designed as a software extension meant to operate within a larger software framework intended for managing medical images.

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[1] Visage 7 is a Class II medical device. It has been cleared with the former trade name Visage PACS/CS under K082269.

Performance Data

Visage Breast Density was tested against two independent data sets of 500 and 700 studies from two different sites. Three board certified radiologists with MQSA qualification per site performed a breast density classification and the consensus of the three reviewers was determined for each study.

The predicted breast density category of Visage Breast Density was related to the ground truth from the clinical reports and the consensus of the three reviewers. The accuracies per category and the total accuracy were computed for the classification into the four categories of the ACR BI-RADS Atlas 5th Edition as well as for the binary classification 'dense' versus 'non-dense'.

The resulting accuracies were compared to the corresponding values of the predicate device. Visage Breast Density achieved similar accuracies per category and similar total accuracies compared to the predicate device.

The validation showed that the results of Visage Breast Density regarding the classification of breast density categories are in sufficient accordance with the results of the predicate device.

Conclusion

The differences in technological characteristics between Visage Breast Density and the predicate device do not raise new questions of safety or effectiveness. The differences in indications for use do not change the intended use nor raise new questions of safety and effectiveness.

Based on the information presented in this premarket notification, and in accordance with the indications for use, technological characteristics and validation testing, it is concluded that Visage Breast Density is substantially equivalent to the predicate device PowerLook Density Assessment.