November 21, 2018

Eigen
William Mandel
Director of Operations, Regulatory Affairs, and Quality Assurance
13366 Grass Valley Ave.
GRASS VALLEY, CA 95945

Re: K173744
Trade/Device Name: ProFuse CAD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 28, 2018
Received: October 10, 2018

Dear William Mandel:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173744

Device Name
ProFuse CAD

Indications for Use *(Describe)*
ProFuse CAD is a post-processing software tool intended for viewing, analyzing, reviewing and reporting imaging files such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT) and Positron Emission Tomography (PET) studies.

The software is able to process time series modality data acquired before, during, and after a contrast agent has been administered to the patient. The software allows a physician to evaluate tissue characteristics based on contrast enhancement visible on the time series. The time series data can also be processed to get subtraction image time –series with any reference time point.

ProFuse CAD also provides capability to process a specialized MRI series called diffusion weighted imaging to evaluate tissue characteristics based on water diffusion. Some of the other posts –processing features include multi-planar reformats and registration between images.

ProFuse CAD has a marking feature that allows the user to outline organs with minimal input and also annotate regions in the image in 3D. The software also allows for grading the annotated regions as defined by the user.
After review, the software automatically generates a patient report that provides information like; organ volume, annotations; and grading along with automatically generated screenshots of the annotations in different images.

Planned data from ProFuse CAD can be used for interventional procedures like MR – TRUS fusion biopsies. The data can be displayed on medical device data systems.

ProFuse CAD is used as a tool to review and add to the results of interventional procedures like; adding pathology information when reviewing MR-TRUS fusion biopsy.

When interpreted by a skilled physician, this device provides information that is intended to be used for screening, analysis, and interventional planning. Patient management decisions should not be made based solely on the results of ProFuse CAD.

ProFuse CAD is intended to be used as an image viewer of multi-modality, digital images, including Ultrasound, CT, PET.

ProFuse CAD is intended to be used in a variety of setting such as; medical offices, clinics, hospital, and home office.

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

K173744

Submitter's Name:	Eigen
Submitter's Address:	13366 Grass Valley Avenue, Grass Valley, CA 95945
Submitter's Telephone:	530-274-1240 x237
Contact Name:	William Mandel
Date Summary was Prepared:	3 Aug 2017
Common or Usual Name:	ProFuse Computer Aided Detection
Trade or Proprietary Name:	ProFuse CAD
Classification Name:	System, Image Processing, Radiological, LLZ Picture Archiving and Communications, 21CFR 892.2050

Device Description

ProFuse CAD is standalone Computer Aided Detection (CAD) software that is used by radiologists to visualize, analyze, plan and interpret medical images using tools available in the software. Some of the tools in the software are

- Visualization: The software allows simultaneous visualization of different images with the ability to view them in different orientations e.g. transverse, sagittal, coronal and 3D.
- Organ segmentation: The software allows user to outline the organ of interest (e.g. prostate)
- Image annotation: The software allows user to mark regions of interest (ROI) on images

- Time-series analysis: The software allows user to view the time-curve plots for a single location or average over a region (ROI). The user could also calculate different parametric maps based on pharmacokinetic modeling. The parametric maps could be viewed as a separate series or be overlaid as color on another series. The software also allows users to calculate subtracting images from a customizable user defined time point.
- Diffusion – series analysis: Diffusion weighted series is a special type of magnetic resonance imaging (MRI) sequence that measures diffusion of water molecules in the body. A set of different diffusion weighted images are obtained and from the set of images the software allows the user to fit different mathematical models to extract different parametric maps. The parametric maps could be viewed as a separate series or be overlaid as color on another series.
- Report: The software allows the user to create reports following either the PIRADS (see definition) standard or a customizable standard.
- Export: The software allows the planned images to be exported for different procedures e.g. biopsy, therapy, etc. Information exported by ProFuse CAD could then be used in other software solutions like ProFuse Bx, ProFuse FP.
- Review: Review, add and modify data from the 3D visualization software (Artemis). The data includes acquired volume, organ segmentation, planned and recorded biopsy location and pathology information.

Primary and Referenced Predicate Devices

Properties	**DynaCAD V1.0 (K041286)** Primary	**iCAD (K091529) (K121517)** Referenced	**ProFuse (K120187)** Referenced	**ProFuse CAD**
Visualization	X	X	X	X
Organ segmentation	X	X	X	X
Image annotation	X	X	X	X
Time-series analysis	X	X		X
Diffusion – series analysis	X	X		X
Report	X	X	X	X
Export	X	X	X	X
Review	X	X	X	X

Intended Use

ProFuse CAD is a post-processing software tool intended for viewing, analyzing, reviewing and reporting imaging files such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT) and Positron Emission Tomography (PET) studies.

The software is able to process Dynamic Contrast Enhanced (DCE) MRI dataset to estimate the pharmacokinetic modeling parameters. The model parameters estimated allows a physician to evaluate tissue characteristics. The DCE data can also be processed to get subtraction image time –series with any reference time point.

ProFuse CAD also provides capability to process a specialized MRI series called diffusion weighted imaging to evaluate tissue characteristics based on water diffusion. Some of the other posts –processing features include multi-planar reformats and registration between images.

ProFuse CAD has a marking feature that allows the user to outline organs and also annotate regions in the image in 3D. The software also allows for grading the annotated regions as defined by the user. After review, the software generates a patient report that provides information like organ volume and region of interest assessment categories along with screenshots of annotations in different images.

Planned data from ProFuse CAD can be used for interventional procedures like MR – TRUS fusion biopsies. The data can be displayed on medical device data systems.

ProFuse CAD is used as a tool to review and add to the results of interventional procedures like; adding lab pathology information when reviewing MR-TRUS fusion biopsy.

When interpreted by a skilled physician, this device provides information that is intended to be used for screening, analysis, and interventional planning. Patient management decisions should not be made based solely on the results of ProFuse CAD.

ProFuse CAD is intended to be used as an image viewer of multi-modality, digital images, including Ultrasound, CT, PET.

ProFuse CAD is intended to be used in a variety of setting such as; medical offices, clinics, hospital, and home office.

Substantial Equivalence:

The product's technical features are substantially equivalent to the DynaCAD V1.0 (K041286) and iCAD (K091529) (K121517). All the features of the ProFuse (K120187) software are included in the ProFuse CAD software. ProFuse CAD is a software product that runs on PC-based workstations. Image data is input to the devices and used to generate 3-D views and perform image processing. Like the three primary and referenced predicate devices, the software has image measurement, multi-planar reformatting, segmentation and image registration abilities, fusion of images from different modalities, image storage and retrieval, as well as patient information management functions.

DynaCAD V1.0 and iCAD is software products that accept multiple image data types including magnetic resonance, computed tomography, and ultrasound. The ProFuse has been designed for processing medical images in standard DICOM format.

ProFuse CAD is build off our previous version, which was 510(k) cleared and contains all of the features in that version. The previous version had the trade name of ProFuse and was all so know as Multi-Modality Image Fusion (MMIF).

Testing and Performance Data:

All product and engineering specifications were verified and validated. Test phantoms incorporating simulated prostates were used only for volume estimation accuracy studies. Simulated and retrospective clinical data were used for verification and validation of the diffusion and perfusion analysis tools.

Safety and Effectiveness

ProFuse CAD labeling contains instructions for use and necessary cautions, warnings and notes to provide for safe and effective use of the device. Risk Management is ensured via ProFuse CAD lRisk Management procedure, which is used to identify potential hazards. These potential hazards are controlled via the product (software) development process, verification and validation testing.

Nonclinical Testing and Performance Information

Nonclinical and performance testing has been performed by designated individuals as required by Eigen's quality procedures. Verification & Validation Test Plans were designed to evaluate all input functions, output functions, and actions performed by ProFuse CAD in each operational mode. ProFuse CAD has been assessed and tested at the manufacturer's facility and has passed all in-house testing criteria including validating design, function and specifications. Measurement validation using, phantoms, clinical images were used to show that ProFuse CAD preforms as well as or better than the other primary and referenced predicate devices and furthermore shows that ProFuse CAD was safe and effective. Nonclinical and performance testing results are provided in the 510(k) and demonstrate that the predetermined acceptance criteria are met. ProFuse CAD has been designed to comply with applicable standards.

Conclusion:

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications of ProFuse CAD with those of the other primary and referenced predicate devices demonstrates that ProFuse CAD is substantially equivalent to existing products on the market today.