GE Medical Systems SCS
% Hong Cui
Regulatory Affairs Director
3000 North Grandview Boulevard-HQ
WAUKESHA WI 53188

November 17, 2020

Re: K193306
Trade/Device Name: PROView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 21, 2020
Received: October 22, 2020

Dear Hong Cui:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193306

Device Name
PROView

Indications for Use *(Describe)*

PROView is an aiding tool for the clinicians to review multi-parametric prostate magnetic resonance (MR) images following PI-RADS guidelines. It displays acquired and reformatted data for visualization and provides tools for assessment of the prostate gland volume and findings analysis in patients with known or suspected prostate lesions. Measurements and associated scoring are included in a report for communication to referring physicians.
It is intended for use by professionals, such as clinicians, radiologists, or physicians. The clinician remains ultimately responsible for the final assessment and diagnosis based on state-of-the-art practices, clinical judgment and interpretation of prostate images or quantitative data.

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.

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 26, 2019
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Hong Cui Regulatory Affairs Director GE Healthcare, (GE Medical Systems, LLC) 3000 N Grandview Blvd., Waukesha, WI - 53188 Phone: (262) 506-8238 Email: hong.cui@ge.com
Secondary Contact Person:	Elizabeth Mathew Senior Regulatory Affairs Manager Phone: (262) 424-7774 Email: Elizabeth.Mathew@ge.com
Proposed Device:	
Device Name:	PROView
Common/Usual Name:	MR image analysis software
Regulation number/ Product Code:	21 CFR 892.2050 Picture archiving and communications system/ LLZ
Classification:	Class II

Predicate Device:

Device Name:	**DynaCAD**
510(k) number:	K192200 cleared on Oct 9, 2019
Regulation number/ Product Code:	21 CFR 892.2050 Picture archiving and communication system / LLZ
Classification:	Class II
Manufacturer:	Invivo Corporation, USA

Device Description/ Technology:

PROView offers a guided workflow for the review, assessment and reporting of multi-parametric MR prostate exams. From inputting clinical information, measuring prostate and lesion volume to scoring lesions to form a comprehensive MR report, PROView offers a simple workflow per PI-RADS™ v2.1 guideline.

PROView Processes data from a single date.

The PROView workflow includes:

- Prostate volume extracted from automatic organ segmentation
- PSA Density
- Lesion(s) mapping to sectors and measurement
- Scoring of T2-weighted, diffusion weighted imaging (DWI) and, when applicable, dynamic contrast enhanced (DCE) acquisitions.
- Automatically generated report with all measurements and images

Prostate volume can be automatically calculated by defining the contours of the prostate gland with the use of a deep learning algorithm, or through a manual method. Users can cancel or switch to manual prostate gland volume definition if the automatic prostate gland segmentation fails or provides unsatisfactory results

Intended Use:

PROView is a medical diagnostic software that is designed to provide easy processing, analysis, reviewing and communication of 3D reconstructed images and their relationship to originally acquired images from MR Scanning devices. The combination of acquired images, reconstructed images, annotations, and measurements performed by the clinician are intended to provide to the referring physician clinically relevant information that may aid in diagnosis and treatment planning.

Indication for Use: PROView is an aiding tool for the clinicians to review multi-parametric prostate magnetic resonance (MR) images following PI-RADS guidelines. It displays acquired and reformatted data for visualization and provides tools for assessment of the prostate gland volume and findings analysis in patients with known or suspected prostate lesions. Measurements and associated scoring are included in a report for communication to referring physicians.

It is intended for use by professionals, such as clinicians, radiologists, or physicians. The clinician remains ultimately responsible for the final assessment and diagnosis based on state-of-the-art practices, clinical judgment and interpretation of prostate images or quantitative data.

Technological Characteristic: The goal of the new PROView software algorithm is to provide an automatic segmentation of the prostate on MRI T2 weighted acquisitions. It is a routine anatomical acquisition (as opposed to functional MRI), routinely done by the clinicians for prostate cancer assessment, as it is part of PIRADS guidelines. The algorithm provides a fully automatic segmentation of the prostate, based on a deep learning model.

Comparison:

The below comparison identifies the similarities and differences of the proposed PROView to the DynaCAD Prostate module of the predicate device DynaCAD (K192200) to which substantial equivalency is claimed.:

Specification	**DynaCAD K192200 (DynaCAD Prostaet)**	**Proposed Device: PROView**
Targeted clinical condition	Male patient with suspected or known prostate lesions	Male patient with suspected or known prostate lesions
Anatomy	Prostate	Prostate
Imaging modality	MRI	MRI
Gland segmentation	Automatically performs a 3D segmentation of the gland. Users can alter or make adjustments to the segmented results in all three planes. The resulting segmentation reports overall gland volume and sets the stage for UroNav MR/US guided fusion	The software provides a fully automatic segmentation of the prostate, based on a deep learning model. Contour of the prostate gland can be adjusted by the user. Prostate volume is extracted from automatic gland segmentation.

	biopsy	
Gland volume	The resulting segmentation reports overall gland volume and sets the stage for UroNav MR/US guided fusion biopsy	Prostate volume is extracted from automatic gland segmentation after validation of the contour by the user.
Segmentation algorithm type	Model-based automatic prostate gland segmentation	Automatic segmentation of the prostate based on a deep learning model.
Standardized report	Following PI-RADS™ v2	Following PI-RADS™ v2.1

Determination of Substantial Equivalence:

PROView has successfully completed the required design control testing per GE's quality system. PROView was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures have been applied to the development of the device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification)
- Safety testing (Verification)
- Algorithm Qualification (Validation)

Engineering has validated PROView algorithm's capability of automatic segmentation based on deep learning technique by using a database of MRI prostate exams. This database of exams is considered as representative of the clinical scenarios where PROView is intended to be used, with consideration of the different protocols, practices and ethnics factors. The results and feedback concluded that the algorithm meets the acceptance criteria and improves performance on volume accuracy.

The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Conclusion:

GE Healthcare considers PROView to be as safe, as effective, and performance is substantially equivalent to the predicate device.