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.


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,

[Signature]

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
Indications 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.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*
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
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   78530 Buc, France

Primary Contact Person: Hong Cui
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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:

<table>
<thead>
<tr>
<th>Specification</th>
<th>DynaCAD K192200 (DynaCAD Prostate)</th>
<th>Proposed Device: PROView</th>
</tr>
</thead>
<tbody>
<tr>
<td>Targeted clinical condition</td>
<td>Male patient with suspected or known prostate lesions</td>
<td>Male patient with suspected or known prostate lesions</td>
</tr>
<tr>
<td>Anatomy</td>
<td>Prostate</td>
<td>Prostate</td>
</tr>
<tr>
<td>Imaging modality</td>
<td>MRI</td>
<td>MRI</td>
</tr>
<tr>
<td>Gland segmentation</td>
<td>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</td>
<td>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.</td>
</tr>
</tbody>
</table>
biopsy

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

**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.