Invivo Corporation
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

August 2, 2021

Re: K212175
Trade/Device Name: DynaCAD
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ LNH
Dated: July 10, 2021
Received: July 12, 2021

Dear Prithul Bom:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212175

Device Name
DynaCAD

Indications for Use *(Describe)*

DynaCAD is a MR image analysis software medical device used during clinical diagnosis, reporting, and interventional pre-planning and is intended to assist the physician through a series of sequential tasks. DynaCAD consists of:

• MR Analysis Server post-processing software application facilitates the analysis of dynamic and non-dynamic MR datasets to provide study review, lesion characterization, and additional mathematical and/or statistical analysis.

• Viewer application facilitates the analysis and presentation of datasets generated by the MR Analysis Server.

• Interventional Planning image-guidance application for diagnostic and interventional procedure planning for biopsy and/or soft tissue ablation.

DynaCAD is indicated for medical conditions that require interventional and/or diagnostic procedures of the prostate gland or breast tissue.

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.

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

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Preparation date: May 18, 2021

Company identification

Invivo Corporation
3545 SW 47th Ave
Gainesville, FL 32608
United States of America
Establishment registration number: 1056069

Contact person

Name: Liselotte Kornmann (primary)
Title: Senior Regulatory Affairs Specialist
Philips Precision Diagnosis Solutions
Telephone: +31611621238
Email: liselotte.kornmann@philips.com

Name: Monique Greijmans (secondary)
Title: Head of Regulatory Affairs
Philips Precision Diagnosis Solutions
Telephone: +31621929674
Email: monique.greijmans@philips.com

Device

Device Trade Name: DynaCAD
Device Class: Class II
Product Code: LLZ
Classification Regulation: 21 CFR, Part 892.2050
Classification Name: Medical image management and processing system
Classification Panel: Radiology

Secondary Product Code: LNH
Classification Regulation: 21 CFR, Part 892.1000
Classification Name: Magnetic resonance diagnostic device
Classification Panel: Radiology

Predicate device

Device Trade Name: DynaCAD
510(k) Number: K192200

Device description

DynaCAD is a MR image analysis software only medical device used during clinical diagnosis, reporting, and interventional pre-planning and is intended to assist the physician through a series of sequential tasks. DynaCAD consists of:

- MR Analysis Server post-processing software application, which facilitates the analysis of dynamic and non-dynamic MR datasets to provide study review, lesion characterization, and additional mathematical and/or statistical analysis. It includes the following software modules: DynaCAD Breast, DynaCAD Prostate, DynaLOC Breast, DynaLOC Prostate, and PK MRI Analysis.
- Viewer application, which facilitates the analysis and presentation of datasets generated by the MR Analysis Server. It includes the following functions: Region of Interest (ROI) curve, Pixel of Interest (POI) curve, Report Card, Volume Calculation, Statistical Analysis, 3-D visualization of image series, and DICOM reporting, among other capabilities.
- Interventional Planning image-guidance application, i.e. Ablation Planning, which facilitates diagnostic and interventional procedure planning for biopsy and/or soft tissue ablation. It helps the user to prepare for ablation procedures by presenting the target regions along with critical structures identified in MR, and previously acquired biopsy data. It provides information about the ablation devices and applicators for automatic ablation plan computation, which the user can adjust as necessary.

DynaCAD is used in both the radiology, i.e. DynaCAD Radiology, and urology domain, i.e. DynaCAD Urology.

Intended use / Indications for use

DynaCAD has the following Indications for Use:

DynaCAD is a MR image analysis software medical device used during clinical diagnosis, reporting, and interventional pre-planning and is intended to assist the physician through a series of sequential tasks. DynaCAD consists of:

- *MR Analysis Server post-processing software application facilitates the analysis of dynamic and non-dynamic MR datasets to provide study review, lesion characterization, and additional mathematical and/or statistical analysis.*
- *Viewer application facilitates the analysis and presentation of datasets generated by the MR Analysis Server.*
- *Interventional Planning image-guidance application for diagnostic and interventional procedure planning for biopsy and/or soft tissue ablation.*

DynaCAD is indicated for medical conditions that require interventional and/or diagnostic procedures of the prostate gland or breast tissue.

The Indications for Use statement of the subject device is similar compared to the currently marketed DynaCAD.
The addition of the Interventional Planning application together with the editorial changes in the Indications for Use statement do not raise any new safety and effectiveness questions. Both the

subject and predicate device can be used for the same medical conditions that require interventional and/or diagnostic procedures of the prostate gland or breast tissue. Furthermore, the Indications for Use of the subject device falls within the intended use of the predicate device and, therefore, the two devices have the same intended use. Both the subject and predicate device are intended to assist the physician through a series of sequential tasks during clinical diagnosis, reporting, and interventional pre-planning.

Summary of technological characteristics

DynaCAD employs the same fundamental technology compared to the currently marketed predicate device. Both devices provide:

- MR Analysis Server post-processing software application, including the same software modules: DynaCAD Breast, DynaCAD Prostate, DynaLOC Breast, DynaLOC Prostate, and PK MRI Analysis.
- Viewer application, including the same functions that facilitates the analysis and presentation of datasets such as Region of Interest (ROI) curve, Pixel of Interest (POI) curve, Report Card, Volume Calculation, Statistical Analysis, 3-D visualization of image series, and DICOM reporting.

The technological differences for the subject device are as follows:

- DynaCAD offers (in addition to the currently cleared radiology workflow) a urology workflow, i.e. DynaCAD Urology, which is customized to the needs of a clinical urologist for pre-planning and post review of biopsy and ablation procedures. It provides functionalities to
    - review and edit (e.g. modify boundary/targets) the segmented MR results received from DynaCAD Prostate,
    - create an ablation plan with Ablation Planning application (also optionally available for DynaCAD Radiology),
    - view results from ablation procedures for post review purpose.

The differences between the subject and the predicate device do not raise any new questions regarding safety or effectiveness.

Summary of non-clinical performance data

Non-clinical performance testing has been performed on DynaCAD to demonstrate compliance with the following international and FDA-recognized consensus standards:

- IEC 62304 Medical device software – Software life cycle processes (Edition 1.1 2015-06). FDA/CDRH recognition number 13-79.
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices (Edition 1.1 2020-06). FDA/CDRH recognition number 5-129.
- ISO 14971 Medical devices – Application of risk management to medical devices (Third Edition 2019-12). FDA/CDRH recognition number 5-125,
- ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (Third Edition 2016-11-01). FDA/CDRH recognition number 5-117,

- NEMA PS 3.1-3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2016). FDA/CDRH recognition number 12-300.

Non-clinical software verification testing has been performed to verify that all functional and non-functional requirements as well as the identified safety and security risk control measures for DynaCAD have been implemented. Results demonstrated that all executed verification test passed.

Software validation testing has been performed to validate that DynaCAD conforms to its intended use, user needs, claims. The validation consisted of the following activities:

- Usability validation was performed with user representatives that fulfil the intended user profile in a simulated use environment. DynaCAD was found to be safe and effective for the intended use, users and use environment.
- In-house simulated use design validation was performed with user representatives that fulfil the intended user profile. The participants executed validation protocols that simulate the user need in the form of a typical DynaCAD clinical workflow. Results demonstrated that all executed validation protocols were passed. DynaCAD conforms to its intended use, claims, and user needs.

All these tests were used to demonstrate that DynaCAD:

- Complies with the aforementioned international and FDA-recognized consensus standards, and
- Meets the acceptance criteria of the device requirements and is adequate for its intended use.

Summary of clinical performance data

The subject DynaCAD did not require clinical performance data to demonstrate safe and effective use.

Conclusions

Non-clinical performance tests ensured that the modification is properly introduced, and the device conforms to its intended use, users and use environment. These tests were used to demonstrate that it is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.