ProKnow LLC
Mr. Salvadore Gerace
Chief Technology Officer
121 Central Park Place
SANFORD, FL 32771 US

January 2, 2019

Re: K182855
Trade/Device Name: ProKnow DS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 8, 2018
Received: October 10, 2018

Dear Mr. Gerace:

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,

Michael D. O'Hara 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)*
K182855

Device Name
ProKnow DS

Indications for Use *(Describe)*
ProKnow DS is a patient data archive, information management, and analytics software system with a focus on the data and images specific to radiation oncology patients. Users may upload digital patient data created by other devices to ProKnow DS to securely archive, display, and analyze the data. Users can view and navigate patient images, drawn anatomy, calculated dose, and plan details derived from the source files. Users can create or edit anatomy structures to be used either prospectively (e.g., as an input to treatment planning) or retrospectively (e.g., for data analysis, research, and outcomes studies). Users can extract metrics for any single patient, or across a collection of patients, then view results as tables or graphically. ProKnow DS is to be used as an accessory system to perform data archive, review, and analysis, and is not to be used for diagnosis, treatment, or as the sole form of plan approval.

Users of ProKnow DS should be trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists, and physicians. Users should be familiar with the different sources of input data (such as images, structure sets, treatment plans, and calculated dose) as well as how to understand and interpret derived metrics (e.g., dose-volume histograms).

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."

PREMARKET NOTIFICATION [510(k)] SUMMARY

(Provided in conformance with 21 CFR 807.92)

Submitter

ProKnow, LLC
121 Central Park Place
Sanford, FL 32771

Phone: 844-405-2170
Fax: 407-322-7546

Contact Person: Salvadore Gerace
Chief Technology Officer

Date Summary Prepared: October 5, 2018

Device Name and Classification

Trade Name: ProKnow DS

Common/Usual Name: Picture Archiving and Communications System (Medical Imaging Software)
Classification Name: System, Imaging Processing, Radiological
Regulation Number: 21 CFR 892.2050
Product Code: LLZ
Regulatory Class: Class II

Predicate Devices

K173636	Velocity	Varian Medical Systems, Inc.
K101707	fullAccess	Fulcrum Medical, Inc.
K071964	MIM 4.1	MIM Software, Inc.

Device Description

ProKnow DS is a Radiation Therapy Picture/Patient Archiving and Communication System (RT-PACS). It allows users to archive, inspect, analyze, and interact with radiation therapy patient data for both retrospective and prospective studies. Its features are centered on two primary areas of interaction: (1) single patient datasets and (2) collections of patient datasets, i.e., patient cohorts. Users are able to import patient data from existing imaging, contouring, and treatment planning systems (via DICOM

formats). Once imported, patient data is archived for long-term storage and is also available for inspection and analysis (examples of supported inspection and analysis tasks include: visualizing images, structures, and dose distributions; inspecting plan information; inspecting dose volume histograms; and extracting metrics). ProKnow DS also allows users to edit anatomical contour data associated with a patient for use in retrospective studies or to be exported to commercially available radiation treatment planning systems. Once a set of patients have been established in ProKnow DS, users may create collections of related patients allowing them to analyze and correlate dosimetric values of interest and clinical endpoints across large treatment populations.

Intended Use

ProKnow DS provides a scalable and secure data archive for binary digital imaging and communications in medicine (DICOM) data with a focus on radiotherapy (DICOM RT). The input data objects are created by other medical devices and uploaded to ProKnow DS for storage and processing. These input medical devices may include imaging systems, manual and auto-contouring systems, treatment planning systems, and other medical software/devices that output applicable data.

ProKnow DS has an interactive viewer that can be used to display and analyze patient data such as images (e.g., CT and MR), contoured anatomical structures, treatment plan information, calculated radiation dose grids, and dose volume histograms (DVH).

ProKnow DS provides anatomy contouring tools for the purpose of (1) creating new anatomy structure sets (i.e., a set of user-defined anatomy contours) and (2) editing structure sets created by another system and uploaded to ProKnow DS. The users' new or edited structure sets can be downloaded in the industry standard DICOM RT Structure Set format to serve as an input to other software systems.

ProKnow DS allows the user to create lists of user-defined metrics, and optionally per-metric performance objectives, which can be extracted and viewed per patient dataset. Metrics can be of two types: (1) derived/computed, which are metrics extracted from the input DICOM objects or computed DVH data, and (2) custom, which are user-defined text or numeric fields and their user-supplied values. Tabulated results are displayed and can be used to facilitate and standardize tasks such as plan evaluation and peer review.

ProKnow DS allows the user to define and track "collections" of patient datasets (i.e., cohorts) from which metrics from all patients in the collection can be extracted and analyzed as a population using interactive graphical tools such as histograms and scatterplots.

Indications for Use

ProKnow DS is a patient data archive, information management, and analytics software system with a focus on the data and images specific to radiation oncology patients. Users may upload digital patient data created by other devices to ProKnow DS to securely archive, display, and analyze the data. Users can view and navigate patient images, drawn anatomy, calculated dose, and plan details derived from

the source files. Users can create or edit anatomy structures to be used either prospectively (e.g., as an input to treatment planning) or retrospectively (e.g., for data analysis, research, and outcomes studies). Users can extract metrics for any single patient, or across a collection of patients, then view results as tables or graphically. ProKnow DS is to be used as an accessory system to perform data archive, review, and analysis, and is not to be used for diagnosis, treatment, or as the sole form of plan approval.

Users of ProKnow DS should be trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists, and physicians. Users should be familiar with the different sources of input data (such as images, structure sets, treatment plans, and calculated dose) as well as how to understand and interpret derived metrics (e.g., dose-volume histograms).

Summary of Technological Characteristics

ProKnow DS is substantially equivalent to the identified predicate devices in terms of characteristics, materials, and features; it also has similar technological features, intended use, and indications for use and does not pose any new issues for safety and effectiveness. It is worth noting that ProKnow DS is a cloud-based system, and therefore must address additional Cybersecurity requirements and risks as part of the design process (as compared to desktop-based devices). These have been addressed and are documented in Section 16 and have been demonstrated through verification and validation testing to not pose any new issues for safety and effectiveness.

A detailed comparison to the identified predicate devices can be found in Section 12.

Summary of Non-Clinical Testing

ProKnow has verified and validated that the ProKnow DS software meets its functional specifications and performance requirements. Verification testing was accomplished using a combination of unit and end-to-end tests; both automated and manual. Verification testing utilized published and analytical gold standard datasets wherever possible. Validation testing was performed by a clinical expert in accordance with the intended clinical use in a simulated clinical environment, as well as by hospital-based and 3rd party vendor validation partners. Validation testing utilized a variety of data types and combinations that were judged to be representative of the types of data the software will encounter in clinical use. The verification and validation test results showed that ProKnow DS met all clinical requirements in terms of usability and accuracy of any/all data stored and displayed. In addition, the test results show that the device is at least as safe and effective as the legally marketed predicate devices.