October 8, 2025

Elekta Solutions AB
Mooud Amirkavei
Senior Regulatory Affairs Specialist
Hagaplan 4
Stockholm, 113 68
Sweden

Re: K251363
Trade/Device Name: ProKnow DS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 1, 2025
Received: September 15, 2025

Dear Mooud Amirkavei:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiaiton Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251363

Please provide the device trade name(s).

ProKnow DS

Please provide your Indications for Use below.

ProKnow DS is intended to be a data archive and processing software which supports review, analytics, and clinical decision-making with a focus on the data specific to radiation oncology patients.

ProKnow DS should be used in healthcare facilities by trained medical professionals including, but not limited to physicians, medical technologists, physicists and dosimetrists.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Traditional 510(k) Summary (21 CFR § 807.92)

I. Submitter

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Contact	Dr. Mooud Amirkavei
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510(k) Number	K251363
Date Prepared	2025-05-01

II. Device

Trade Name	ProKnow DS
Bran Name	ProKnow DS, Elekta One Plan Analytics
Product Classification	Class II
Common Name	Medical image management and processing system
Regulation Number	892.2050
Product Code	LLZ

III. Predicate Device

Predicate #	K182855
Predicate Trade Name	ProKnow DS
Predicate Product Code	LLZ

IV. Device Description Summary

ProKnow DS provides a high-performance, scalable medical image management and processing system. 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 physical models 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.

V. Intended Use/ Indications for Use

ProKnow DS is intended to be a data archive and processing software which supports review, analytics, and clinical decision-making with a focus on the data specific to radiation oncology patients.

ProKnow DS should be used in healthcare facilities by trained medical professionals including, but not limited to physicians, medical technologists, physicists and dosimetrists.

VI. Intended Use/ Indications for Use Comparison

Update of intended use/indication for use statement was to distinguish it from customer requirements and allows the use of ProKnow for clinical decision support. The contraindication for ProKnow stating 'not to be sole source of plan approval' is being removed.

The general purpose of the ProKnow DS and its functions remains the same.

VII. Technological Comparison

ProKnow DS is to provide a high-performance, scalable medical image management and processing system. It allows users to archive, inspect, analyze, quantify, and interact with radiation therapy patient data for both retrospective and prospective studies.

ProKnow DS now provides the following features:

- Enabling 3D image registration: Manual 3D image registration provides the ability to manually create, edit and download spatial registration objects (SRO) between 3D image sets in different frames of reference (FOR). A series of tools will be introduced to allow users to easily fuse image sets in different coordinate systems.

- Opportunity dose volume histograms (Opportunity DVH): This feature makes use of the new Opportunity DVH algorithm which is made available in ProKnow DS. The Opportunity DVH is used to determine the theoretical limit of structure sparing if a set of targets are treated to the prescribed dose. Comparisons to the achieved dose can be visualized by overlaying the Opportunity DVH brands on the DVH curves for a plan.

The fundamental technological characteristics of the subject device ProKnow DS have not changed with the addition of 3D image registration and Opportunity DVH functionality and are substantially equivalent to its predicate device cleared under K182855. Table 1 below compares features of the subject device, and the predicate device cleared under K182855 across multiple aspects of the device.

Table 1: Comparison table of the technological characteristics of the subject and predicate devices

Item category description	Item identifier	Predicate device (K182855) ProKnow DS 1.0	Subject device ProKnow DS 2.1	Comparison discussion	
Intended use and indications for use statement	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 permetric performance objectives, which can be extracted and viewed per patient dataset. Metrics can be of two types: (1) derived, which are metrics extracted from the input DICOM objects or computed DVH data, and (2) custom,*	ProKnow DS is intended to be a data archive and processing software which supports review, analytics, and clinical decision-making with a focus on the data specific to radiation oncology patients. ProKnow DS should be used in healthcare facilities by trained medical professionals including, but not limited to physicians, medical technologists, physicists and dosimetrists.	Substantially equivalent	The general purpose of the device and its functions is not affected. The proposed intended use and indications for use statement fall within the intended use/indication for use of the predicate device. The proposed intended use/indication for use statement does not raise different questions of safety and effectiveness. The clinical context, target disease, and patient population for the subject device are the same as those of the predicate device.

Item category description	Item identifier	Predicate device (K182855) ProKnow DS 1.0	Subject device ProKnow DS 2.1	Comparison discussion	
		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.*	ProKnow DS is intended to be a data archive and processing software which supports review, analytics, and clinical decision-making with a focus on the data specific to radiation oncology patients. ProKnow DS should be used in healthcare facilities by trained medical professionals including, but not limited to physicians, medical technologists, physicists and dosimetrists.	Substantially equivalent	The general purpose of the device and its functions are not affected. The proposed intended use and indications for use statement fall within the intended use/indication for use of the predicate device. The proposed intended use/indication for use statement does not raise different questions of safety and effectiveness.

Item category description	Item identifier	Predicate device (K182855) ProKnow DS 1.0	Subject device ProKnow DS 2.1	Comparison discussion	
		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).			
Use environment	Environment	Access-controlled healthcare facilities	Access-controlled healthcare facilities	Identical	No changes have been made to the use environment since K182855 clearance, therefore no documentation is being provided in this 510(k) related to Environment, documentation cleared under K182855 continues to support the subject device.
	User	Trained healthcare professional.	Trained healthcare professionals.	Identical	
Human factors	User interface controls	Product compliant with IEC 62366-1	Compliant with IEC 62366-1	Substantially equivalent	Subject Device ProKnow DS 2.1 complies to IEC 62366-1. The updates to the user interface since K182855 clearance were driven by customer feedback as part of product improvement and did not impact the safety or efficacy of ProKnow DS. Changes were evaluated during the usability study and found to be compliant to IEC 62366-1.
Design and Performance	Software algorithms	-DVH algorithm; -DICOM visualizer algorithm; -Algorithm for draw and paint, expand, interpolate and merge (for contouring, review and analysis)	-Opportunity DVH algorithm, --3D image registration, -DVH algorithm; -DICOM visualizer algorithm; -Algorithm for draw and paint, expand, interpolate and merge (for contouring, review and analysis),	Substantially equivalent	-Addition of opportunity DVH algorithm is complementary to the existing DVH algorithm. It provides the user with additional DVH information but does not remove or replace any existing functionality that would significantly affect the clinical use of the product. -3D image registration did not exist in the predicate device and will be introduced as new feature of subject device. However, the Introduction of 3D image registration preserves the visualization of objects in the same frame of reference which was already supported in the predicate device.

Item category description	Item identifier	Predicate device (K182855) ProKnow DS 1.0	Subject device ProKnow DS 2.1	Comparison discussion	
					-DICOM visualizer algorithm in the subject device is now being provided by the RT visualizer component. There is no impact to the user or the outputs as the functionality provided is equivalent. -No changes to other algorithms.
Design and Performance	Software deployment methods	Software/Cloud ProKnow stores in the cloud but renders client side on the Desktop.	Software/Cloud ProKnow stores in the cloud but renders client side on the Desktop.	Identical	No changes have been made to the software deployment method since K182855 clearance.
Critical performance requirements: Manual contouring as well as Data archive, review and analysis	MANUAL CONTOURING: Able to contour (draw) anatomy outlines atop medical images and export in industry standard format (DICOM RT Structure Set)	Yes	Yes	Identical	N/A
	DATA ARCHIVE: User interface to interactively view/review stored patient data	Yes	Yes	Identical	N/A
	DATA REVIEW: Storage device for medical images (DICOM) and radiotherapy (DICOM RT) data objects, including plan, structure set, and dose	Yes	Yes	Identical	N/A
	DATA ANALYSIS: Compute and/or derive DVH metrics and other key metrics from the input source data;	Yes	Yes	Substantially equivalent	The DVH data type for the subject device and the predicate device are equal. Improvements to handle edge cases and avoid calculation failures has been added to the subject device. Additional computed DVH metric types have been added. Opportunity DVH bands may be viewed at the same time as DVH.

Item category description	Item identifier	Predicate device (K182855) ProKnow DS 1.0	Subject device ProKnow DS 2.1	Comparison discussion	
	DATA ANALYSIS: Allows user to aggregate data and extra metrics across a multitude of patients	Yes	Yes	Identical	N/A
Standard compliance	Safety and performance	NEMA PS 3.1 - 3.20-2016 ISO 13485 ISO 14971 IEC 62304 IEC82304-1 IEC 62083 IEC 62366-1 IEC 61217 IEC 81001-5-1 ISO 15223-1 ISO 20417	ISO 13485 ISO 14971 IEC 62304 IEC82304-1 IEC 62083 IEC 62366-1 IEC 61217 IEC 81001-5-1 ISO 15223-1 ISO 20417 NEMA PS 3.1 - 3.20-2024	Substantially equivalent	As applicable, the product has been updated to comply with latest version of the standards.
Compatibility with the environment, other devices, and accessories	Compatibility with Connected Systems	Compatible with devices that have DICOM interface	Compatible with devices that have DICOM interface	Identical	N/A

VIII. Summary of Performance Testing (Non-Clinical)

Testing in the form of manual and automated verification were performed to evaluate the performance and functionality of the new features against requirement specification.

Regression test of unchanged functionalities in the subject device was done to ensure that new and updated functionalities did not introduce any undesirable effects.

Design validation of the device have been performed by competent and professionally qualified personnel to ensure that the product fulfils the intended use and user needs. The design validation also ensured that the risk control measures associated with functions related to safety for the affected functionality were effective.

Results from verification and validation testing demonstrate that conformance to applicable technical requirement specification and user needs have been met and that the device functions as intended.

IX. Summary of Performance Testing (Clinical)

No animal or clinical tests were performed to establish substantial equivalence with the predicate device. The performance data demonstrate that the subject device is as safe and effective and performs as well as the predicate devices (K182855).

X. Substantial Equivalence Conclusion

ProKnow DS is claimed to be substantially equivalent (SE) to the predicate ProKnow DS (K182855).

The refined verion of intended use/indication for use statement was to distinguish it from customer requirements and allows the use of ProKnow for clinical decision support. The general purpose of the ProKnow DS and its functions remains the same. The contraindication for ProKnow stating 'not to be sole source of plan approval' is now being removed in the subject device based on the accumulated changes to existing functions that support clinical decision making.

The fundamental technological characteristics of ProKnow DS have not changed with the addition of 3D image registration functionality.The device safety and performance have bene addressed by non-clinical testing in conformance with predetermined performance criteria, FDA guidance, and recognized consensus standards. Table 2 below lists the FDA guidance documents and standards for the device.

The result of verification and validation as well as conformance to relevant safety standards demonstrate that ProKnow DS meets the established safety and performance criteria and is substantially equivalent to the predicate device (K182855).

Table 2: List of FDA guidance documents and standards for ProKnow DS

FDA guidance documents	
Issue date	**Title**
2023-08-11	Off-The-Shelf Software Use in Medical Devices
2016-12-28	Post-market Management of Cybersecurity in Medical Devices
2016-02-03	Applying Human Factors and Usability Engineering to Medical Devices
2020-07-29	Multiple Function Device Products: Policy and Considerations
2017-09-06	Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices
2014-07-28	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
2023-06-14	Content of Premarket Submissions for Device Software Functions
2023-09-27	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Recognized Consensus Standards	
IEC 62366-1 Ed. 1.1 2020-06	Medical devices - Part 1: Application of usability engineering to medical devices (Rec. 5-129)
ANSI AAMI IEC 62304:2006/A1:2016	Medical device software – Software life cycle processes (Rec. 13-79)
IEC 62083 Ed. 2.0 2009-09	Medical Electrical Equipment –Requirements for the Safety of Radiotherapy Treatment Planning Systems (Rec. 12-217)
IEC 61217 Ed. 2.0 2011-12	Radiotherapy Equipment – Coordinates, Movements, and Scales (Rec. 12-267)
NEMA PS 3.1-3.20 2024e	Digital Imaging and Communications in Medicine (DICOM) Set (Rec. 12-363)
IEC 82304-1 Ed 1.0 2016-10	Health software - Part 1: General requirements for product safety (Rec.13-97)
IEC 81001-5-1 Ed.1.0 2021-12	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle (Rec. 13-122)
ISO 15223-1:2021 Ed. 2021-07	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements (Rec. 5-134)
ISO 20417 Ed. 2021-04 Corrected version 2021-12	Medical devices - Information to be supplied by the manufacturer (Rec. 5-135)
ANSI AAMI ISO 14971: 2019	Application of risk management to medical devices (Rec. 5-125)