October 25, 2021

Elekta Solutions AB
% Anju Kurian, M.S., RAC
Manager, Regulatory Affairs - Software
1450 Beale Street, Suite 205
SAINT CHARLES MO 63303

Re: K212218
Trade/Device Name: Advanced Algorithms for Treatment Management Applications (AATMA™)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB, LLZ
Dated: September 8, 2021
Received: September 16, 2021

Dear Anju Kurian:

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)*

K212218

Device Name

Advanced Algorithms for Treatment Management Applications (AATMA™)

Indications for Use *(Describe)*

AATMA™ is a medical image processing library intended to produce derived data sets for use as input into radiation therapy treatment planning systems or other intermediate pre-treatment-planning applications. AATMA™ does not provide a user interface and is designed to be accessed through its application programming interface (API) by other devices. The data sets created by AATMA™ must be reviewed and validated by a qualified healthcare professional prior to clinical use.

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.

TRADITIONAL 510(K) SUMMARY (21 CFR § 807.92)

I. SUBMITTER

	Elekta Solutions AB Kungstensgatan 18 Box 7593 Stockholm, Stockholms lan [SE-01] SE SE10393
Contact:	Anju Kurian, M.S., RAC Manager, Regulatory Affairs - Software
Establishment Registration #:	3015232217
510(k) Number:	K212218
Date Prepared:	10/18/2021

II. DEVICE

Trade Name:	AATMA™ (Advanced Algorithms for Treatment Management Applications)
Release Version #:	Release 1.0
Product Classification:	Class II
Common Name:	Radiological Image Processing Software for Radiation Therapy
Classification Name:	Medical Image Management and Processing System
Regulation Number:	21 CFR § 892.2050
Product Code:	QKB/LLZ

III. PREDICATE DEVICE

Workflow Box by Mirada Medical (K181572)

IV. DEVICE DESCRIPTION

AATMA™ is an optional accessory to treatment planning systems and intermediate pre-treatment planning applications. The auto-segmentation algorithm in AATMA™ is based on machine-learning convolutional neural networks and includes pre-trained models that will be used to automatically segment image sets. The algorithm itself functions as a computational engine and does not store any input data, output data, or logs. The available models have been pre-trained on specific datasets that exhibit similar characteristics (e.g., body site and imaging modality).

As a medical image processing library, AATMA™ is designed to produce derived datasets in standard formats (e.g., DICOM) that can be utilized by other applications. AATMA™ does not have a user interface and, as such, calling applications must

execute the auto-segmentation algorithms via AATMA™'s application programming interface (API).

AATMA™ must be used in conjunction with appropriate software to review and edit results generated automatically by the auto-segmentation algorithm. A pre-treatment planning system or treatment planning system must be used to facilitate the review and edit of contours generated by the auto-segmentation algorithm within AATMA™.

V. INTENDED USE

AATMA™ is a medical image processing library intended to produce derived data sets for use as input into radiation therapy treatment planning systems or other intermediate pre-treatment-planning applications. AATMA™ does not provide a user interface and is designed to be accessed through its application programming interface (API) by other devices. The data sets created by AATMA™ must be reviewed and validated by a qualified healthcare professional prior to clinical use.

VI. INDICATIONS FOR USE

AATMA™ is a medical image processing library intended to produce derived data sets for use as input into radiation therapy treatment planning systems or other intermediate pre-treatment-planning applications. AATMA™ does not provide a user interface and is designed to be accessed through its application programming interface (API) by other devices.

The data sets created by AATMA™ must be reviewed and validated by a qualified healthcare professional prior to clinical use.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Technological Characteristic	**AATMA™ (Subject Device**	**Workflow Box Predicate Device K181572**
Automatic contouring of imaging data using machine learning based models	✓	✓
No Graphical User Interface	✓	✓
View manipulation and Volume rendering – Not Applicable	✓	✓
Image registration	N/A	✓
Reporting and Data Routing	N/A	✓
Supported modalities: Standard DICOM image modality support	✓ Subject device validated with CT images for image processing.	✓ Predicate device validated with CT, MR, DICOM RTSTRUCT for image processing.
TCP/IP Networking and Communication	✓	✓

VIII. SUMMARY OF PERFORMACE TESTING (NON-CLINICAL)

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

AATMA™ is validated and verified against its user needs and intended use by the successful execution of planned performance, functional and algorithmic testing included in this submission. The results of performance, functional and algorithmic testing demonstrate that AATMA™ meets the user needs and requirements of the device, which are demonstrated to be substantially equivalent to those of the listed predicate device.

Verification and Validation for AATMA™ has been carried out in compliance with the requirements of CFR 21 Part 820 and in adherence to the DICOM standard.

Performance testing for two models – Head & Neck, Male Pelvis were conducted.

The Head & Neck model was trained on 66 unique clinical patient 3D CT image sets from a variety of institutions and equipment. A different set of six(6) patient CT image sets with expert contours were chosen for verification and the average DICE coefficient over all structures was determined to be 0.84 which met the defined acceptance criteria. A different set of 13 3D CT image sets were used for validation and these met the acceptance criteria as well.

The Male Pelvis model was trained on 205 unique patient 3D CT image sets from a global variety of institutions and equipment from patients undergoing RT. A different set of five (5) patient CT image sets with expert contours were chosen for verification and the average DICE coefficient over all structures was determined to be 0.93 which met the defined acceptance criteria. A different set of 20 3D CT image sets were used for validation and these met the acceptance criteria as well.

IX. SUMMARY OF PERFORMACE TESTING (CLINICAL)

No animal or clinical tests were performed to establish substantial equivalence with the predicate device. The performance data demonstrate that AATMA™ is as safe and effective and performs as well as the predicate device Workflow Box by Mirada Medical cleared under K181572.

X. SUBSTANTIAL EQUIVALENCE CONCLUSION

In conclusion, performance testing and device evaluations presented in this 510(k) demonstrates that AATMA™ is substantially equivalent to and performs at least as safely and effectively as the listed predicate device. AATMA™ meets the requirements for safety and effectiveness as applicable to radiological image processing software and does not introduce any new potential safety risks.