ScandiDos AB
% Daniel Pederson
QA & RA Manager
Dag Hammarskjölds väg 52A
Uppsala, Uppland 752 37
SWEDEN

January 16, 2024

Re: K223234
Trade/Device Name: Delta4 Insight
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: December 1, 2023
Received: December 12, 2023

Dear Daniel Pederson:

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.

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
Radiation 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

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)*
K223234

Device Name
Delta4 Insight

Indications for Use *(Describe)*
Delta4 Insight is a software intended to provide quality assurance of radiotherapy treatment plans by an independent dose calculation.

Delta4 Insight is not a treatment planning system or a radiation delivery device. Information provided by Delta4 Insight shall not be used to directly modify or influence radiation treatments. Delta4 Insight is to be used only by trained radiation oncology personnel for quality assurance purposes.

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.

510(K) SUMMARY

1 APPLICANT

510(k) owner's Name	ScandiDos AB
Street address	Dag Hammarskjölds väg 52A
Postal Code, City	SE-75237 Uppsala
Country	Sweden
Phone Number (mobile)	+46-73-502 81 50
Fax Number	+46-18-10 74 02
Name of official correspondent	Daniel Pederson
Date the summary was prepared (yyyy-mm-dd)	2023-12-01

2 DEVICE

Trade Name	Delta4 Insight
Common/Usual Name	Secondary Check QA Software
Device Classification Name	Medical charged-particle radiation therapy system (§892.5050)
Product code	IYE

3 PREDICATE DEVICES/

Predicate Devices	Registered Establishment Number	510(k) Premarket submission number
SciMoCa	3009140718	K180595

4 DESCRIPTION OF THE DEVICE

Delta4 Insight is software specifically design for quality assurance of radiotherapy treatment plans generated by a treatment planning system. The device calculates a secondary dose calculation via an independent Monte-Carlo based dose calculation software and compares this to the treatment planning system dose. The device is used as a secondary check for the results of a TPS and not for comparison with a measurement.

Delta4 Insight is a software module within the General Delta4 software. The software module is independent of all other software modules within the Delta4 software. The device is NOT a treatment planning system or a radiation therapy delivery device. It is only used by trained radiation therapy oncology personnel for the purposes of quality assurance in a hospital setting.

Insight supports treatments with MV photons. No other radiation type is supported.

5 INTENDED USE OF THE DEVICE

Delta4 Insight is a software intended to provide quality assurance of radiotherapy treatment plans by an independent dose calculation.

Delta4 Insight is not a treatment planning system or a radiation delivery device. Information provided by Delta4 Insight shall not be used to directly modify or influence radiation treatments. Delta4 Insight is to be used only by trained radiation oncology personnel for quality assurance purposes.

The intended use of the new device is contained within the intended use of the predicate device.

6 SAFETY AND ESSENTIAL PERFORMANCE

The following standards apply to the device (general use):
IEC 62304:2006/A1:2016

7 PERFORMANCE DATA

The following performance data were provided in support of substantial equivalence:

Software verification and validation testing
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." Validation testing involved testing of clinical treatment plans and simulated clinical workflows and environment. Verification tests were performed to verify the product performed to specification and functions as it was designed. These tests include tests to verify requirements for functionality, accuracy,

compatibility, tests to ensure risk mitigations function as intended, and regression tests to ensure the safety and effectiveness of functionality.

Test plans
Non-clinical testing was conducted in accordance with the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]."
The dose from anonymized DICOM patient treatment plans from chosen reference algorithms were re-calculated with Insight and the dose compared. Test plans were chosen to span the space of test parameters for the types of treatment types/modalities/energies/TPS/machines that are supported. The variety of plans tested are reflective of common clinical treatments and tumor sites and span many field sizes and tissue depths. The results were analyzed using a gamma comparison between Insight dose results and the original reference TPS dose.

Summary
The device passed verification and validation testing and was deemed safe and effective for its intended use. All test plans passed using a similar criteria to that of the predicate. Based on results of this testing the device was found to have a safety and effectiveness profile similar to the predicate device, supporting the claim of substantial equivalence.

8 TECHNOLOGICAL COMPARISON WITH THE PREDICATE DEVICES

The primary technological components of the device and its predicate device are an independent dose calculation algorithm and functionality that allows comparison between an independently-calculated dose and a dose generated by a treatment planning system, all for quality assurance purposes. The technological characteristics are believed to be substantially equivalent to the predicate device. This is summarized in the table below:

Area	**SciMoCa (primary predicate Device)**	**Delta^4 Insight**
Intended Use	SciMoCa is a software product intended to provide quality assurance of a radiotherapy dose calculated by a treatment planning system by allowing a clinician to re-calculate the dose with an independent dose calculation algorithm and compare the two doses. SciMoCa is not a treatment planning system or a radiation delivery device. It is to be used only by trained radiation oncology personnel for quality assurance	Delta4 Insight is a software intended to provide quality assurance of the radiotherapy treatment process by an independent dose calculation. Delta4 Insight is not a treatment planning system or a radiation delivery device. Information provided by Delta4 Insight shall not be used to modify or influence radiation treatments. Delta4 Insight is to be used only by trained radiation oncology personnel for quality assurance purposes.

	purposes.	
Intended User	The intended user is a health care professional in the field of radiotherapy like a medical physicist or a dosimetrist who have been educated in the safe use of the device.	Same as predicate device
Spatial use context	The device is a software program used on a computer in a radiotherapy department	Same as predicate device
Social use context	Only health care professionals have access to the software. See "Intended user"	Same as predicate device
Hygienic use context	N/A- Software program	Same as predicate device
Physical use context	The device is a software program installed on a computer in a radiotherapy department. Radiotherapy departments have highly controlled environmental conditions to allow for patient comfort. The temperature is typically very stable at about 22 Cº. Also, the humidity is typically controlled (non condensing, 30-70%),	Same as predicate device
Activity use context	Independent calculation of radiotherapy dose is set up to calculate automatically. User can access and analyze results using the program just like any other PC program- often by sitting in front of the screen and interacting with a mouse and short phrases of text. No further physical interaction is required.	Same as predicate device
Biocompatibility	N/A- Software program	Same as predicate device
Communication	TCP/IP protocol between server and clients through hospital network. Input files sent to server via DICOM protocol.	Same as predicate device
Energy delivered	No energy is delivered.	Same as predicate device

	Device is a software	
Intended medical indication	See “Intended Use”	See “Intended Use”
Intended patient population	Verification of treatment plans of patients undergoing radiotherapy treatments-typically curative or palliative treatments	Same as predicate device
Intended part of the body or type of tissue applied to or interacted with	The device is never applied to a body part. No patients ever interact with the device. No patients are ever intended to touch the PC. The device is a software.	Same as predicate device
Intended user profile	See “Intended user”	See “Intended user”
Intended condition of use (environment, including hygienic requirement, frequency of use, location, mobility)	See “IntendedUse environment”	See “Intended Use environment”
Sterile or non sterile	N/A the device is a software. PC (not part of the device) is non-sterile	Same as predicate device
Single or re-usable	N/A device is a software	Same as predicate device
Hospital or home use	The device is used in a radiotherapy device in a hospital	Same as predicate device
Measured quantity	Software uses input from the treatment planning system for an independent dose calculation.	Same as predicate device
Operating Principle	The software is independent of any measuring device or treatment planning system. The software receives data from the treatment planning system and independently calculates dose. The user can then analyze the dose calculated with the software and compare with the dose from the treatment planning system.	Same as predicate device

	Various metrics are available for analysis.	
Software analysis	Comparing TPS dose with dose calculated from PC program	Same as predicate device
Dose calculation engine type	Monte Carlo	Same as predicate device
Dose calculation engine & viewing station arrangement	Dose calculated on a server inside hospital. User can access results from multiple devices which are on the same network.	Same as predicate device
Main inputs	TPS dose, plan, CT, and structures. Beam model information and CT to density table.	Same as predicate device
Commissioning data collection	Machine specific beam information (proprietary beam modeling)	Same as predicate device
Dose reporting type	Dose to water or dose to medium	Same as predicate device
Accuracy/Performance of calculation	When comparing the dose calculation results of patient plans to a reference algorithm (Acuros), 97% of the dose voxels with more than 5% of the maximum dose pass a gamma criteria of 2%/2mm [Hoffman et al, *Validation of the Acuros XB dose algorithm versus Monte Carlo for clinical treatment plans*. MedPhys 2018 June 16].	Calculation results of patient plans to a reference algorithm (Monaco, Acuros) have a similar gamma pass rate to that of the predicate.

Although proprietary details of the calculation algorithms differ, the technological characteristics of the device are the same as the predicate. The intended use of the new device is contained within the intended use of the predicate device. Performance test plans using the device passed with a similar gamma criteria to that of the predicate.

9 CONCLUSIONS

The non-clinical performance data support the safety of the device and the software verification and validation demonstrate that the device performs as intended in the specified use conditions.

Performance test plans using the device passed with a similar gamma criteria to the predicate, demonstrating that the device performs comparably to the predicate device that is currently marketed for a comparable intended use. It is the opinion of Scandidos AB that the device, Delta4 Insight, is as safe, is as effective, and performs as well as the predicate device.