DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 19, 2015

ScandiDos AB
% Mr. Thomas Matzen
Product Manager
Dag Hammarskjölds väg 52A
SE-75237 Uppsala
SWEDEN

Re: K151180
Trade/Device Name: Delta^4 Phantom+
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 22, 2015
Received: July 22, 2015

Dear Mr. Matzen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

D017 04 008 02 a-001_06_1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151180

Device Name
Delta4 Phantom+

Indications for Use *(Describe)*
The intended use of the device is:
• quality assurance of patient specific treatment delivery prior to the treatment in IMRT (including VMAT) and 4DRT (e.g. respiratory gating and tumour tracking).
• quality assurance of the radiation delivery system.

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.

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Version	Comment	Author	Description
01.01	2015-04-27	Thomas Matzen	First Draft
01	Released	Thomas Matzen	No changes
02	Released	Thomas Matzen	Corrected Spelling mistake in IEC standard Added non-clinical test comparison

1 APPLICANT

510(k) owner's Name	ScandiDos AB
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Name of official correspondent	Thomas Matzen
Date the summary was prepared (yyyy-mm-dd)	2015-07-17

2 DEVICE

Trade Name	Delta^4 Phantom+
Common Name	Pre-treatment Verification System (for Quality Assurance)
Classification Name	Medical charged-particle radiation therapy system, §892.5050, Product code: IYE

3 PREDICATE DEVICE

Predicate Device	Delta4
Listing Number	D002954
510(k) Premarket submission number	K052920

4 DESCRIPTION

The device consists out of matrices of semiconductors embedded in a phantom. These matrices are inserted into the radiation field of a medical linear accelerator. If radiation (from a radiotherapy treatment field) hits the semiconductors a signal is created and transferred to a computer where it is analysed and among others compared with the intended dose distribution.

5 COMPARISON

5.1 General

The Delta^4 Phantom+ dosimetry system is an improved version of its predicate device Delta^4.

The most obvious improvement is that the Delta^4 Phantom+ dosimetry system is wireless: no power cables, no trig cable and no data cables.

Otherwise the principal design is left unchanged.

5.2 Use context

Area	**Delta^4 (predicate device)**	**Delta^4 Phantom+**	**Comment**
Intended Use	The intended use of Delta^4 is quality assurance of patient specific treatment delivery prior to the treatment in IMRT and 4DRT (respiratory gating and tumor tracking).	The intended use of the device is • quality assurance of patient specific treatment delivery prior to the treatment in IMRT (including VMAT) and 4DRT (e.g. respiratory gating and tumour tracking). • quality assurance of the radiation delivery system.	*The intended use definitions are almost identical. However, the text had been changed slightly to ease understanding.* • *VMAT is just a special form of intensity modulated treatment and is by definition included in "IMRT". However, sometimes "VMAT" is used as if it was something different. For clarification VMAT is named in the intended use of Phantom+ explicitly.* • *pre treatment delivery quality assurance includes quality assurance of machine parameters. For clarification QA of the radiation delivery system is named explicitly in the intended use of Phantom+.*

Area	Delta^4 (predicate device)	Delta^4 Phantom+	Comment
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	*N/A*

5.3 Energy

Area	Delta^4 (predicate device)	Delta^4 Phantom+	Comment
Power supply	AC power socket	Battery powered. (Rechargeable) Battery is embedded in device.	*While the predicate device must be connected to the a socket-outlet is the Delta^4 Phantom+ dosimetry system battery powered.* *This makes it much more convenient to set up the device.*
Energy delivered	No energy is delivered to user or patient	Same as predicate device	*N/A*

5.4 Performance, technology, materials

Area	Delta^4 (predicate device)	Delta^4 Phantom+	Comment
Operating principal	The device consists out of matrixes of semiconductors embedded in a phantom. These matrixes are inserted into the radiation field of a medical linear accelerator. If radiation (from a radiotherapy treatment field) hits the semiconductors a signal is created and transferred to a computer where it is analysed and among others compared with the intended dose distribution.	Same as predicate device	*N/A*
Detector technology	Semiconductors	Same as predicate device	*N/A*

Area	Delta^4 (predicate device)	Delta^4 Phantom+	Comment
Detector placement	Two 2D arrays; the arrays are mounted in a 3D phantom	Same as predicate device	*N/A*
Shape: Dimensions Phantom	Cylinder, 22x40cm	Same as predicate device	*N/A*
Dimension phantom including electronics housings	• Length: About 72cm • Total height when in lowest position: about 36cm • Center height when in lowest position: about 18cm	• Length: About 71cm • Total height when in lowest position: about 28cm • Center height when in lowest position: about 15.5cm	• *Practically and from the safety and effectiveness point of view there is no difference between the devices regarding overall length.* • *The new device has lower phantom supports. The new phantom supports do not block the longitudinal alignment laser at all. Therefore the set up and the alignment of the new device is more convenient, safer and more effective compared to the predicate device.* • *The center height has been lowered by some centimeters in the new device. This increases the clearance between the linac and the treatment couch for beams from beneath the couch with reduced risk for collision between linac and couch - the set up of the new device is therefore safer, more convenient and more effective compared to the predicate device.*
Weight	About 27kg	Same as predicate device	*N/A*
Main Analysis parameters	• Dose Difference • Distance to agreement • Gamma index	Same as predicate device	*N/A*

5.5 Communication

Area	Delta^4 (predicate device)	Delta^4 Phantom+	Comment
Communication software ←→ access point/ router	Via an ethernet cable connected the PC is connected directly with the access point/router.	Same as predicate device	*N/A*
Communication Access point/ router ←→ measuring hardware	Via Ethernet cables.	Wi-Fi 802.11n	*By eliminating the ethernet cable to the hardware the risk for entangling (rotating gantry) has been eliminated. This makes the usage both safer and also more convenient and effective (set up is much faster).* *The communication protocol used is a widely spread standard protocol (used in hospitals, homes, offices) guaranteeing a safe and effective use of the new device.*

5.6 (Safety) Standards met

Area	Delta^4 (predicate device)	Delta^4 Phantom+	Comment
Standards met	• IEC 61010-1 • IEC 60601-1-2	Same as predicate device	*N/A*

5.7 Biocompatibility

Area	Delta^4 (predicate device)	Delta^4 Phantom+	Comment
General	Device is never in contact with patients	Same as predicate device	*N/A*
Compatibility of Phantom material	Good, see 21CFR886.1385 (PMMA)	Same as predicate device	*N/A*

5.8 Compatibility with the environment and other devices, safety (mechanical, chemical, physical, thermal, radiation)

Area	Delta^4 (predicate device)	Delta^4 Phantom+	Comment
General	Device fulfils the essential requirements as defined in the "Council Directive 93/42/EEC of 14 June 1993 concerning medical devices" (MDD)	Same as predicate device	*N/A*

5.9 Sterility

Area	Delta^4 (predicate device)	Delta^4 Phantom+	Comment
General	Device is not intended to be sterile	Same as predicate device	*N/A*

5.10 Comparison with predicate

Comparison tests have been performed with the predicate device in clinical and non-clinical situations.
Among others pre-treatment verification measurements of numerous treatment plans have been performed with both the new device and the predicate device. The results were compared with each other and it was determined that the results had very good correlation.

6 SUMMARY

The new device is superior or at least equivalent, in many cases identical with the predicate devices regarding safety, effectiveness, design and performance.