DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 29, 2016

ScandiDos AB
% Mr. Thomas Matzen
Product Manager
Dag Hammarskjolds vag 52A
Uppsala, SE-75237 Uppsala Lan
SWEDEN

Re: K151426
Trade/Device Name: "Delta^4 Discover, and "Delta^4 Discover+"
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 28, 2015
Received: December 28, 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,

Michael D. O'Hara For

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

Enclosure

D012 04 045 01 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)*
K151426

Device Name
"Delta4 Discover" and "Delta4 Discover+"

Indications for Use *(Describe)*

The intended use of the device is

· quality assurance of patient specific treatment delivery during and before external radiotherapy treatment, including IMRT, VMAT and 4DRT (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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Document Title: **FDA 510(k) - Summary - Delta4 Discover** Subject: **Delta4 Discover**		Document ID: D012 04 016 01	Page 002_06_1 (002_06_2)
Author: Thomas Matzen	Signature	Date	

D012 04 016 01 FDA 510(k) - Summary - Delta4 Discover.docx

Version	Comment	Author	Description
01	Released	Thomas Matzen	First release

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	+46-18-472 30 30
Fax Number	+46-18-10 74 02
Name of official correspondent	Thomas Matzen
Date the summary was prepared (yyyy-mm-dd)	2015-05-20

2 DEVICE

Trade Name	"Delta^4 Discover" and "Delta^4 Discover+"
Common/Usual Name	QA device for verification of radiotherapy treatments and treatment plans
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
PTW DAVID IMRT QC verification system	9681124	K062817
IBA Compass	9614952	K072374

4 DESCRIPTION OF THE DEVICE

The device is an instrument specifically designed to be used to check delivered treatment plans by medical accelerator systems used for radiation therapy applications for quality assurance (QA) purposes.

The device consists of a 2-dimensional matrix of semiconductors and associated acquisition, display and analysis computer programs. It is a quality assurance (QA) device enabling detailed mapping of therapeutic radiation dose distributions. This dose information is used in both quantitative and subjective assessments of the performance of radiation therapy treatment planning systems and therapeutic radiation delivery systems.

The detector matrix is inserted into the radiation field of a medical linear accelerator. If radiation (from a radiotherapy treatment field) hits the detectors a signal is created and transferred to a computer where it is evaluated (e.g. by comparing planned with measured dose distributions).

5 INTENDED USE OF THE DEVICE

The intended use of the device is

- quality assurance of patient specific treatment delivery during and before external radiotherapy treatment, including IMRT, VMAT and 4DRT (respiratory gating and tumour tracking)
- quality assurance of the radiation delivery system.

6 SAFETY AND ESSENTIAL PERFORMANCE

The new device is designed in full accordance with the applicable sections of the following standards:

- IEC 60601-1
- IEC 60601-1-2

7 TECHNOLOGICAL COMPARISON WITH THE PREDICATE DEVICES

All devices are intended for quality assurance of patient specific treatment delivery and quality assurance of the radiation delivery system.

Based on the technological characteristics, the intended use, safety and effectiveness, essential performance, performance the new device is substantially equivalent to the predicate devices.

The documentation submitted for review supports this claim.

8 SUMMARY

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