



April 20, 2020

C-Rad Positioning AB
% Mr. Thomas Matzen
Director Quality and Regulatory Affairs
Bredgränd 18
Uppsala, Uppsala 75320
SWEDEN

Re: K200600

Trade/Device Name: Sentinel
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: March 23, 2020
Received: March 23, 2020

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. 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

Indications for Use

510(k) Number (if known)

K200600

Device Name

Sentinel

Indications for Use (Describe)

The system is intended for use in radiation therapy clinics together with diagnostic or treatment equipment and provides:

- accurate and reproducible patient positioning.
- a respiratory signal to be supplied to diagnostic imaging equipment (primarily CTs) for prospectively and retrospectively (aka 4DCT) gated imaging and reconstruction.

The system cannot directly determine the location of the intended treatment target, since only the patient external surface is detected. The actual target position must therefore, whenever deemed necessary by qualified personnel, be verified using other systems such as CBCT or EPID.

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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510(k) Summary**K200600****Owner:**

C-Rad Positioning Ab
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Establishment registration no:

3006621300

Contact person:

Ellinor Nami
Regulatory Affairs Specialist
Phone no: +46 (0)18 410 82 36

Date of preparation:

February 24, 2020

Trade name of device:

Sentinel
Sentinel 4DCT

Common name:

Radiotherapy positioning system

Classification name:

Medical charged-particle radiation therapy system
Regulation: 21 CFR 892.5050

Product code: IYE

Predicate marketed device(s):

Sentinel (K120668)

Device description:

The Sentinel hardware consists of a single scanner unit containing the laser and camera, mounted in the ceiling in front of the CT. The scanner is connected to the PC running the c4D software. During patient surface acquisition, a laser line is swept along the patient while the camera records a number of images. From the data acquired, a complete 3D surface of the patient can be reconstructed using laser line triangulation. On this surface the user, a health care professional, virtually marks where on the patient the respiratory motion signal shall be measured and in the next step, when the 4DCT imaging starts, the signal is measured with a frequency of around 16Hz. In general, the system is capable of acquiring more than 50 contours per second. The acquired 3D surface can also be exported and used as a reference image in the treatment room.

The Sentinel system for the CT room is used in radiation therapy clinics to ~~perform prospective or retrospective gated imaging (4DCT) prior to treatment. The system~~

provides information about a patient's respiratory motion during the localization of the tumour in CT imaging. The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostics departments.

The Sentinel platform is based on advanced laser technology with multipurpose software modules covering different tasks in the diagnostic procedure. The software is user friendly and requires a minimum of user interaction in the daily clinical workflow. The software is designed to integrate with existing CT systems at the clinic. The Sentinel system does not require any markers to be placed on the patient or the couch and doesn't subject the patient to any additional radiation. This also means that the personnel can stay in the CT room during the whole set up procedure.

Sentinel for the CT room includes the cRespiration module for respiratory gating during diagnostic CT imaging, so called 4D CT studies.

cRespiration

The Sentinel system allows you to perform prospectively or retrospectively gated imaging (4DCT) and with an interface to the CT system the user can easily integrate cRespiration to the clinical work flow with improved accuracy in the CT room. cRespiration allows you to have two detection points which enables both thoracic and abdominal breathing motions to be detected in parallel.

Intended use:

The system is intended for use in radiation therapy clinics together with diagnostic or treatment equipment and provides:

- accurate and reproducible patient positioning.
- a respiratory signal to be supplied to diagnostic imaging equipment (primarily CTs) for prospectively and retrospectively (aka 4DCT) gated imaging and reconstruction.

The system cannot directly determine the location of the intended treatment target, since only the patient external surface is detected. The actual target position must therefore, whenever deemed necessary by qualified personnel, be verified using other systems such as CBCT or EPID.

Technological comparison:

The Sentinel system is substantially equivalent to its predicate device Sentinel (K120668) in terms of their technological characteristics and its safety and efficacy profile.

The Sentinel system has been used in both treatment room and CT room in radiotherapy clinics. However, since 2017 it has only been used and supported in the CT room. The change we made to the intended use reflects the actual usage of the system to show that we no longer support patient motion supervision in treatment rooms. Based on a business decision this feature has been withdrawn for new sales and hence the intended use has been updated by removing the option of patient motion supervision in treatment room. This change does not have any effect on the validation and verification activities performed on the system.

The c4D software version 6.0.0 is supporting 64-bit architecture. In earlier versions the software was only supporting 32-bit architecture. In c4D 6.0.0 all program components have been compiled for 64-bit architecture. The functionality of the software with respect to the 64-bit support is unchanged. Complete re-verification has been performed to verify that the design outputs meets the design inputs after the change from 32-bit to 64-bit support.

Safety and effectiveness:

Performance data has been submitted to show that Sentinel achieves its intended use and that the software update and rephrasing of intended use raise no new issues of safety or efficacy.