



May 7, 2020

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

Re: K200435

Trade/Device Name: Catalyst+, Catalyst+ HD, Catalyst, Catalyst HD,
Catalyst Tomo, Catalyst PT

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical charged-particle radiation therapy system

Regulatory Class: Class II

Product Code: IYE

Dated: February 20, 2020

Received: February 24, 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)

K200435

Device Name

Catalyst+, Catalyst+ HD, Catalyst, Catalyst HD, Catalyst Tomo, Catalyst PT

Indications for Use (Describe)

The Catalyst+ system and accessories are intended for use in radiation therapy clinics with treatment equipment, to provide:

- Interactive guidance for setup and positioning of patients for radiation therapy
- Intra-fraction motion detection during radiation therapy
- Respiratory gating during radiation therapy

The device is not intended for use in MR-linac systems.

The system shall only be used by hospital personnel, qualified to work in radiation therapy departments. Training on the use of the system will be given to users at the time of installation.

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 - K200435

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 20, 2020

Trade name of device:

Catalyst⁺, Catalyst⁺ HD
Catalyst, Catalyst HD
Catalyst Tomo, Catalyst PT

Common name:

Radiotherapy positioning system

Classification name:

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

Predicate marketed device(s):

Catalyst (K113276)

Device description:

The Catalyst⁺ product consists of projector unit hardware and Windows based software. The product is intended to be used in radiation therapy clinics for patient positioning, patient monitoring and respiratory gating.

A 3D image of the patient surface can be acquired and compared to a reference image that was either imported from e.g. a treatment planning system, or acquired by surface scanning earlier. The Catalyst⁺ system computes the optimal couch correction as well as errors in the patient's posture.

Measurements are done continuously using near UV light (405 nm). The detected errors are in parallel projected using visible light (red and green) in real-time e.g. as a distance map directly on the patient's surface to indicate which body parts that need to be adjusted and

how. The rigid-body couch correction is projected numerically and can be sent to the couch control system to enable auto-setup of the couch.

Once that patient is in the correct position, the Catalyst⁺ system will continue to monitor the patient during treatment delivery to ensure that it doesn't move out of position. If a large movement is detected, a warning can be issued for the personnel to react on, and/or an interlock can be triggered automatically to shut off the beam.

For optimal coverage of the patient and to support couch kicks, two additional units (Catalyst⁺ system without back projection) can be installed in an angle from the main unit. The configuration is called Catalyst⁺ HD/PT.

The following application modules are provided:

- cPosition – is the application module that provides a reproducible way of accurately positioning patients. It compares the current patient position with a reference setup by using surface matching software for calculating adjustments in the patient's position.
- cMotion – is the application module for supervising patient motion during treatment. During treatment the system shall record the patient's position continuously and signal or interrupt treatment when the patient is moving outside specified tolerance intervals.
- cRespiration – is the application module for respiratory tracking and gating. During treatment the module is able to give a warning or to turn the beam on or off depending on the acquired respiratory signal and on the gating parameters established in the treatment plan. The cRespiration in Catalyst⁺ is based on reference data created in the CT room.

Intended use:

The Catalyst⁺ system and accessories are intended for use in radiation therapy clinics with treatment equipment, to provide:

- Interactive guidance for setup and positioning of patients for radiation therapy
- Intra-fraction motion detection during radiation therapy
- Respiratory gating during radiation therapy

The device is not intended for use in MR-linac systems.

The system shall only be used by hospital personnel, qualified to work in radiation therapy departments. Training on the use of the system will be given to users at the time of installation.

Technological comparison:

The Catalyst⁺ system is substantially equivalent to its predicate device Catalyst (K113276) in terms of intended use and technological characteristics as well as its safety and efficacy profile.

The hardware changes introduced to the Catalyst⁺ system consists of the replacement of the old optical 3D scanner devices with new 3D-scanners. The new scanners are based on the same optical 3D scanning technology. The change was driven by an EOL (End of Life) situation of the camera in the old scanner. The supplier and the basic

principle of the scanner (structured light) are unchanged but improvements of primarily the camera has been introduced. To give the Catalyst⁺ a more compact and modern look and feel, the scanner chassis have been redesigned. As the new chassis and interior mechanical designs have been well verified and approved to constitute no new risks or decrease in performance.

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 the Catalyst⁺ system achieves its intended use and that the hardware and software updates raise no new issues of safety or efficacy.