Brainlab AG
% Chiara Cunico
Manager RA
Olof-Palme-Str. 9
Munich, 81829
GERMANY

April 29, 2022

Re: K220338
Trade/Device Name: ExacTrac Dynamic
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: February 3, 2022
Received: February 18, 2022

Dear Chiara Cunico:

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,

Julie Sullivan, Ph.D.
Assistant Director
Nuclear Medicine and Radiation Therapy Branch
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

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.

Submission Number *(if known)*

K220338

Device Name

ExacTrac Dynamic (1.1)

Indications for Use *(Describe)*

ExacTrac Dynamic is intended to position patients at an accurately defined point within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures, to monitor the patient position and to provide a beam hold signal in case of a deviation in order to treat lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

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

April 22, 2022

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9; 81829, Munich, Germany
Establishment Registration	8043933
Device Name	Medical charged-particle radiation therapy system
Trade Name	ExacTrac Dynamic
Product Code	IYE
Regulation Number	892.5050
Regulatory Class	II
Panel	Radiology
Predicate Devices	**ExacTrac Dynamic (K201276)**

1. Indications for Use

ExacTrac Dynamic is intended to position patients at an accurately defined point within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures, to monitor the patient position and to provide a beam hold signal in case of a deviation in order to treat lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

2. Device Description

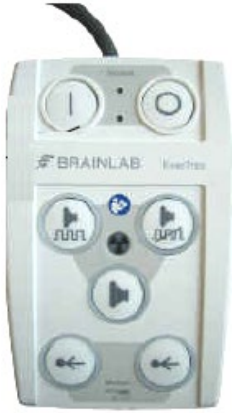
ExacTrac Dynamic is a patient positioning device used in a radiotherapy environment as an add-on system to standard linear accelerators. It uses patient planning and CT data to determine the patient's planned position and compares it via oblique x-ray images to the actual patient position. The calculated correction shift will then be transferred to the treatment machine to align the patient correctly at the machine's treatment position. During treatment the patient is monitored with a surface camera and X-ray to ensure no misalignment due to patient movement.

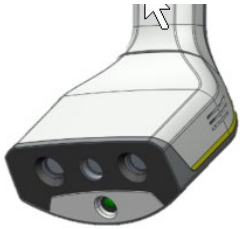
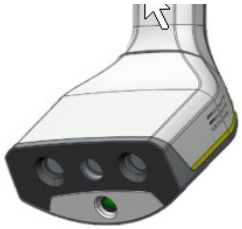
ExacTrac Dynamic 1.1 is a modification of the previously cleared device ExacTrac Dynamic 1.0 that additionally features a Deep Inspiration Breath-Hold (DIBH) functionality to treat breast cancer. This functionality helps correctly position the patient to a deep inspiration breath-hold level and then to monitor this position using surface tracking and x-ray positioning technology. This functionality was not included in ExacTrac Dynamic 1.0. The aim of this technology is to treat the patient only during breath-hold phases where the breast is at a defined position with a maximum distance to critical structures like the heart. Additionally, the surface tracking functionality was extended, which monitors the patient after an initial 3rd party positioning.

3. Substantial Equivalence

Features	ExacTrac Dynamic 1.0 K201276 (Primary Predicate)	ExacTrac Dynamic 1.1 (Subject Device)	Comments
Indications for Use	ExacTrac Dynamic is intended to position patients at an accurately defined point within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures, to monitor the patient position and to provide a beam hold signal in case of a deviations in order to treat lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.	ExacTrac Dynamic is intended to position patients at an accurately defined point within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures, to monitor the patient position and to provide a beam hold signal in case of a deviations in order to treat lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.	No changes
Localization technique	The camera detects both the patient surface and the patient thermal surface which together, can be used to track the patient geometries. Stereo X-ray is acquired and compared with the planned position (room based). CBCT data are imported from a from 3rd party CBCT Device and compared with the planned position.	The camera detects both the patient surface and the patient thermal surface which together, can be used to track the patient geometries. Stereo X-ray is acquired and compared with the planned position (room based). CBCT data are imported from a from 3rd party CBCT Device and compared with the planned position.	Same as the predicate device.
General workflow: Patient preparation before using ExacTrac	Uses implanted radio opaque fiducial markers or using Body Markers Performing CT scan Data import from treatment planning system	Uses implanted radio opaque fiducial markers or using Body Markers Performing CT scan Data import from treatment planning system	Same patient preparation method as the predicate
Software User Management	Done via Windows user management according to our instructions	Done via Windows user management according to our instructions	Identical to the predicate

Features	ExacTrac Dynamic 1.0 K201276 (Primary Predicate)	ExacTrac Dynamic 1.1 (Subject Device)	Comments
Deep Inspiration Breath-Hold (DIBH)	N/A	ExacTrac Dynamic 1.1 features a Deep Inspiration Breath-Hold (DIBH) functionality to treat breast cancer. This functionality includes special features and workflows to correctly position the patient to a deep inspiration breath-hold level and then to monitor this position using the ExacTrac surface tracking and x-ray positioning technology. The aim of this technology is to treat the patient only during breath-hold phases where the breast is at a defined position with a maximum distance to critical structures like the heart. These feature results in an optional use of the patient feedback system.	New feature added
Surface Only	N/A	Additionally, a separate workflow offers the possibility to position the patient with a third-party positioning device e.g., CBCT. The patient position defined by the third-party device can be set as a reference for ExacTrac Dynamic which allows monitoring the patient using ExacTrac's surface camera and X-ray system relative to this position. ExacTrac Dynamic 1.1 shall offer performing this third-party positioning and ExacTrac Dynamic monitoring workflow by only using the surface tracking system – contrary to ExacTrac Dynamic 1.0 where it was necessary to acquire X-ray images to set the third party defined patient position as a reference for ExacTrac Dynamic	New feature added
X-ray Generator	The X-ray Generator consists of two HFe 601 X-ray Generators. Each generator controls one X-ray tube. Software control of X-ray settings. Updated electronic board for the updated tubes.	No change compared to ExacTrac Dynamic 1.0	No changes

Features	ExacTrac Dynamic 1.0 K201276 (Primary Predicate)	ExacTrac Dynamic 1.1 (Subject Device)	Comments
ExacTrac Console	ExacTrac Console (System start/shut down, X-ray acquisition) 	ExacTrac Console (System start/shut down, X-ray acquisition) 	No change
X-ray Sources	Varex G-892 Sources (Housing: Varex B-130)	Varex G-892 Sources (Housing: Varex B-130)	No change
Flat Panel Detector including Power Supply	Flat Panel Detector Varex PaxScan 3030DX	no change compared to predicate	No change

Features	ExacTrac Dynamic 1.0 K201276 (Primary Predicate)	ExacTrac Dynamic 1.1 (Subject Device)	Comments
Cameras	3D and Thermal Cameras Manufacturer (3D): Cognex Ireland Limited Type: A5060 Manufacturer (Thermal): Flir Systems AB Type: A65 F25  The camera is used to detect the patient's thermal and spatial surface. The thermal topology is used to prevent the surface registration algorithm from falling into local minima. Thus, both surfaces are used to track patient's position.	3D and Thermal Cameras Manufacturer (3D): Cognex Ireland Limited Type: A5060 Manufacturer (Thermal): Flir Systems AB Type: A65 F25  The camera is used to detect the patient's thermal and spatial surface. The thermal topology is used to prevent the surface registration algorithm from falling into local minima. Thus, both surfaces are used to track patient's position.	no change

Features	ExacTrac Dynamic 1.0 K201276 (Primary Predicate)	ExacTrac Dynamic 1.1 (Subject Device)	Comments
Wall mounted Touch Screen Monitor			No change
			No change
On Floor X-ray sources covers	X-ray tubes within On-Floor Boxes X-ray Tubes within Floor	X-ray tubes within On-Floor Boxes X-ray Tubes within Floor	No change

Features	ExacTrac Dynamic 1.0 K201276 (Primary Predicate)	ExacTrac Dynamic 1.1 (Subject Device)	Comments
In Floor	The In-Floor is used to install on Varian and Elekta LINAC's	Update of In- Floor Covers including a yellow light and updated design.	Update of design, including added light. No functional change
Patient Feedback System	Not included	The Patient Feedback System helps patients visualize their own respiration and to achieve a correct breath hold. Therefore, the mirror is attached the patient head and they can see the in Room Monitor. The Monitor shows the live respiratory status and the DIBH Gating Window. The System is only for supporting the patients, a treatment without is also possible.	New part introduced due to the addition of DBIH feature.
X-ray Calibration			No change
Camera Calibration	Thermal to 3D Calibration Phantom A phantom to calibrate the 3D camera and the thermal camera added.	Thermal to 3D Calibration Phantom A phantom to calibrate the 3D camera and the thermal camera added.	No change

4. Performance Data

The following tests were conducted:

- Compatibility Tests:
- Cybersecurity Tests:
  - ETD Pen Test
  - Vulnerability Test
- Accuracy Test: The test objective is to verify that accuracy specifications for positioning and monitoring of ExacTrac Dynamic are not affected by the selected workflow, treatment parameters and different phantom positions. Also, within this test plan the correct display of deviation indicators and X-ray/DRR overlays as well as the correct transfer and adjustment of shifts and rotations to the patient support system.
- Biological Evaluation: It examines the materials used in the device, considers the application of biological and chemical tests, and the history of safety and efficacy of the device materials in humans.
- Usability Evaluation
- Routine Software verification to confirm that the specifications met the requirements

Clinical Validation

For the new feature, a clinical evaluation was performed which was based on literature review, performance evaluation on phantoms and a clinical investigation for DIBH.

Overview of the Pre-market, single-center Clinical Investigation:

Since the functionality to generate a respiratory signal is new to the Subject Device, a clinical investigation was performed to evaluate the surface camera system-based components of the ETD DIBH module.

Study Objectives:

1. ETD can assist a human - eligible for DIBH (Paul Keall, 2006) - to reproduce a defined state of deep inspiration breath-hold (DIBH) within +/- 3 mm.
2. Regarding the pre-positioning within the DIBH workflow based on ETD's 3D' surface imaging, the surface of a patient - being in state of free-breathing - can be pre-positioned with a translational accuracy better than 6 mm.

Study population: 13 female subjects.

The first study population (patient population), consisted of subjects who are women who were diagnosed with breast cancer that is indicated for a treatment with radiation therapy with the DIBH technique and who are currently, or who have currently been treated with this technique.

The second study population (volunteer population) consisted of subjects who are healthy women who resembled patients that are typically diagnosed with breast cancer as far as possible, concerning their physiognomy and age, and who can perform sufficiently deep and long DIBHs.

All acceptance criteria for the successful completion of the study were passed. No adverse events or adverse device deficiencies were observed.

5. Conclusion

Based on the clinical and non-clinical testing conducted for the Subject Device as listed above and based on the Substantial Equivalence discussion, the Subject Device was demonstrated to be as safe and effective as the predicate device.