Brainlab AG
% Sadwini Suresh
QM Consultant
Olof-Palme-Str.9
Munich, 81829
GERMANY

May 11, 2023

Re: K231052
Trade/Device Name: ExacTrac Dynamic (1.1.2)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: April 11, 2023
Received: April 13, 2023

Dear Sadwini Suresh:

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,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.05.11 11:34:19 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
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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.

510(k) Number *(if known)*
K231052

Device Name

ExacTrac Dynamic (1.1.2)

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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BRAINLAB

510(k) Summary

K231052

May 11, 2023

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 1.1.2
Product Code	IYE
Regulation Number	892.5050
Regulatory Class	II
Panel	Radiology
Predicate Devices	ExacTrac Dynamic 1.1 (K220338)
Contact Information	
Primary Contact	Sadwini Suresh QM Consultant, Regulatory Affairs Phone: +49 89 99 15 68 0 Email: regulatory.affairs@brainlab.com
Alternate Contact	Chiara Cunico Senior Manager Regulatory Affairs Phone: +49 89 99 15 68 0 Email: chiara.cunico@brainlab.com

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 1.1.2 is a modification of the previously cleared device ExacTrac Dynamic 1.1 that 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. 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.

The main functionalities has remained same for the Subject Device. The modifications are done on a specification level to implement additional measures.

3. Performance Data

In order to address the identified bugs, certain specifications and tests related to the bug fixes (as detailed in Section 4) with ExacTrac Dynamic 1.1.2 were modified to include additional measures. These modified specifications were verified via incremental tests. All tests were passed.

4. Substantial Equivalence

The Subject Device has similar functionality, intended use, technological characteristics, and typical users as the predicate device. The change was performed to correct the identified bugs in the predicate device ExacTrac Dynamic 1.1.

The bug fix did not require any change to the existing software architecture.

The following critical bug was identified:

Short name / Specification	Bugzilla ID	Description
procedure without beam hold control – Amiens (Case-20221124-451154)	Bug 154505	In the Treatment application it is possible to treat a DIBH patient with disabled beam control, i.e. if a DIBH plan is prepared with disabled beam control, treatment is not blocked.

The following specifications were added for this bug:

- In the Prep Application the software shall check the setting “Beam Control” of a DIBH Patient and shall not allow to save a DIBH patient with beam control disabled.
- In the Template Editor it shall not be possible to save a new customer template if the DIBH workflow is selected and automatic “Beam Control” is disabled.
- In the Treatment App during the patient opening the setting “Beam Control” of a DIBH Patient shall be checked and in case Beam Control is disabled the patient shall not be loaded.

In addition, the following bugs were also fixed for the Subject Device version:

Table 1: List of Bugfixes

Short name	Bugzilla ID	Description
No deletion is possible although archiving proxy is configured	155619	it is not possible to delete patient without previously have pressed archive button although the data is already archived automatically through the implementation of the bug 154028.
Possibility to achieve Monitoring having positioned with a setup beam which has different isocenter	155252	For plans containing an additional setup beam with a "virtual" isocenter, i.e. an isocenter different than the isocenter of the treatment beam, it is possible to position and treat the patient on the virtual isocenter instead on the treatment isocenter.

Short name	Bugzilla ID	Description
There is a wrong dependency/rule that excludes ContentManager 2.8	155034	Wrong dependency in the top level package
DIBH procedure without beam hold control – Amiens (Case-20221124-451154)	154506	In the Template Editor it is possible to prepare a DIBH template with disabled beam control, i.e. that ETD has no beam control.
X-ray shifts missing in the localized PDF printout	151144	In the localized (translated) pdf printout, no X-ray shifts are printed.
PDF not created after treat	154556	PDF not created after treatment, wrongly created with RepeatExport Bug related to 153990 from testing of RC2
Too many DRRs saved	153990	ETD saves 3 DRRs per X-ray Each DRR is 1MB approx. This is a huge amount of data saved that actually the users do not use but occupies hard disc making the search of patient and loading a patient very slow.
Surfaces are saved every time the surface goes OoT	152130	Surfaces are saved every time the surface goes out-of-tolerance (OOT) during patient monitoring, even if only for a fraction of a second.
Crash during closing app in Monitoring (after SurfaceTrackingOutOfToleranceTreatmentEvent)	154422 (Consequence out of Bug 152130)	Crash when closing application in monitoring.
Crash during closing app in Monitoring (during treatment session saving)	154423 (Consequence out of Bug 152130)	Crash when closing application in monitoring.
Improve 'send shift'/'Go to Treatment' behavior for verification with excluded and zeroed out big rotations in ImplM WF	151687	In the implanted marker WF it is possible to exclude big rotations and zero them out in surface tracking. However, if the rotational shifts are higher than 5°, they will always cause an 'Out of Tolerance' in monitoring (even if they are excluded and zeroed out), causing a beam hold event, which forces a verification and sending a (minimal) shift is always required to continue the treatment. This causes many problems for Users that do have an internal rule to always verify the position again after the couch has been moved.
toplevelbips of ETD 1.1.2 do not install all required packages	154327	When performing a new installation using the ETD toplevelbip the following bip packages are not selected for installation
Upgrade ContentManager 2.7/2.8 with custom settings	154333	-
SW Crash on Sending Shift in OAR Verification	154385	-
TC test: different reference pictures because of different fusion matrix	154449	-

Short name	Bugzilla ID	Description
Gantry angle based X-ray triggered too early (Elekta)	154093	Gantry angle based X-ray is triggered too early for Elekta.
Usergroup check is performed on current user, not user communicated by PDM	125826	ETD uses Windows users instead of PDM users.
Patient deletion fails for certain data sets	152829	-
Patient positioning based on wrong isocenter possible in Verification after Monitoring in rare cases	154002	A Setup Beam that was scheduled for the previous patient and was not used, however it was loaded at the end of the treatment by an automatic function of the Linac. Exactrac detected the beam loading at the Linac and waited for user's confirmation. Instead, the user closed the plan and the patient at the Linac. ExacTrac software seems to expect no plan closing event at the Linac while ETD is in Monitoring. The user was informed via message that "Beam has changed on the Linac" and confirmed it. At this point the software could either crash or proceed, presumably depending on the memory state, In case the software proceeds, the beam is loaded and the user can proceed with the X-Ray Verification. In this case the shift would be based on the isocenter of the mistaken loaded beam, from the previous patient.
Crash after X-ray acquisition on X-ray Correction or Acquisition page	154035	Crash after X-ray acquisition on X-ray Correction or Acquisition page.
[DIBH] ETD Crashes when clicking twice fast on " Confirm level of today"	148088	By click twice fast on "Confirm Level of Today" the software crash.
Wrong level of drawn Gating Window in Frozen View of DIBH Navigation	148462	Having acquired an X-ray in DIBH Navigation causes the view to freeze. All information as available in the point in time of X-ray acquisition is visualized / summarized.
Too sensitive Couch Movement Check for Elekta Precise couches	154087	Too sensitive Couch Movement Check for Elekta Precise couches in the DIBH workflow.
[PrePos] [DIBH] Prepositioning fails after DIBH treatment	150403	For every patient that is loaded on ETD immediately after a DIBH treatment, the Prepositioning contour is not shown.
ETD can treat despite overdue Thermal to 3D calibration	150600	Patients can be treated despite overdue thermal-to-3D camera calibration in case the following conditions are fulfilled: first treatment section of this patient, unprepared patient, and first ETD patient of the day.
Wrong x-ray shift for beams with different PSA in implanted marker monitoring	150933	Wrong x-ray shift in Monitoring for beams with different PSA in implanted marker monitoring

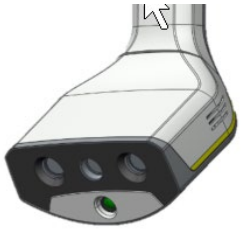
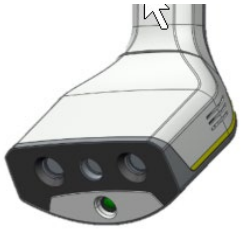
Short name	Bugzilla ID	Description
Surfaces are saved every time the surface goes OoT	152130	Surfaces are saved every time the surface goes out-of-tolerance (OOT) during patient monitoring, even if only for a fraction of a second.
Missed following automatic X-ray trigger acquisition(s) (counter-clockwise beam)	154022	first X-ray at 90° is triggered correctly when gantry is at 96.9° following acquisitions (0° and 270°) are missed, as the SW does not expect more acquisitions beyond the gantry angle of 96.6°
Support Archiving Service	154028	Currently ETD applications are not supporting the Archiving Proxy feature of archiving in a network disk feature of the DICOMProxy.
Gantry angle based X-ray was triggered too early	154093	Automatically gantry-triggered X-rays were acquired too early due to one-time variations of the gantry velocity.

There was no change of intended use, technological characteristics or typical users.

Table 2: Comparison between the Subject Device and Predicate

Features	ExacTrac Dynamic 1.1 K220338 (Primary Predicate)	ExacTrac Dynamic 1.1.2 (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.

Features	ExacTrac Dynamic 1.1 K220338 (Primary Predicate)	ExacTrac Dynamic 1.1.2 (Subject Device)	Comments
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
Deep Inspiration Breath-Hold (DIBH)	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	ExacTrac Dynamic 1.1.2 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.	No change
Surface Only	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 ExacTracs 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	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 ExacTracs surface camera and X-ray system relative to this position. ExacTrac Dynamic 1.1.2 shall offer performing this third party positioning and ExacTrac Dynamic monitoring workflow by only using the surface tracking system.	No change

Features	ExacTrac Dynamic 1.1 K220338 (Primary Predicate)	ExacTrac Dynamic 1.1.2 (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
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 1.1 K220338 (Primary Predicate)	ExacTrac Dynamic 1.1.2 (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
Patient Feedback System	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 a the live respiratory status and the DIBH Gating Window. The System is only for supporting the patients, a treatment without is also possible	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 a the live respiratory status and the DIBH Gating Window. The System is only for supporting the patients, a treatment without is also possible.	No change.

Features	ExacTrac Dynamic 1.1 K220338 (Primary Predicate)	ExacTrac Dynamic 1.1.2 (Subject Device)	Comments
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