January 14, 2026

Brainlab SE
Sadwini Suresh
QM Consultant
Olof-Palme-Str.9
Munich, BY 81829
Germany

Re: K254010
Trade/Device Name: ExacTrac Dynamic (2.0.2); ExacTrac Dynamic Surface
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: December 12, 2025
Received: December 15, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254010

Please provide the device trade name(s).

ExacTrac Dynamic (2.0.2);
ExacTrac Dynamic Surface

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K254010

510(k) Summary

January 09, 2025

General Information	
Manufacturer	Brainlab SE Olof-Palme-Str.9 Munich, 81829 Germany
Establishment Registration	8043933
Device Name	ExacTrac Dynamic 2.0.2
Trade Name	ExacTrac Dynamic; ExacTrac Dynamic Surface
Classification Name	Medical charged-particle radiation therapy system
Product Code	IYE
Regulation Number	892.5050
Regulatory Class	II
Panel	Radiology
Predicate Device and K Number	K240431; ExacTrac Dynamic 2.0

Contact Information	
Primary Contact	**Alternate Contact**
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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 (ETD) is a patient positioning and monitoring device used in a radiotherapy environment as an add-on system to standard linear accelerators (linacs). It uses radiotherapy treatment plans and the associated computed tomography (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 thermal-surface camera and X-ray imaging to

ensure that there is no misalignment due to patient movement. Positioning and monitoring are also possible in combination with implanted markers. By defining the marker positions, ExacTrac Dynamic can position the patient by using X-rays and thereafter monitor the position during treatment.

Additionally, ExacTrac Dynamic features a breath-hold (BH) functionality to serve as a tool to assist respiratory motion management. This functionality includes special features and workflows to correctly position the patient at a BH level and thereafter monitor this position using surface tracking. Regardless of the treatment indication, a correlation between the patient's surface and internal anatomy must be evaluated with Image-Guided Radiation Therapy. The manually acquired X-ray images support a visual inspection of organs at risk (OARs). The aim of this technique is to treat the patient only during breath hold phases where the treatment target is at a certain position to reduce respiratory-induced tumor motion and to ensure a certain planned distance to OARs such as the heart. In addition to the X-ray based positioning technique, the system can also monitor the patient after external devices such as Cone-Beam CT (CBCT has been used to position the patient).

The ExacTrac Dynamic Surface (ETDS) is a camera-only platform without the X-ray system and is available as a configuration which enables surface-based patient monitoring. This system includes an identical thermal-surface camera, workstation, and interconnection hardware to the linac as the ETD system. The workflows supported by ETDS are surface based only and must be combined with an external IGRT device (e.g., CBCT).

3. Substantial Equivalence

For the Substantial Equivalence determination, comparison of the Subject Device features with the following predicate device(s) was carried out:

K240431; ExacTrac Dynamic 2.0

The predicate was chosen since it's the predecessor version and similar to the subject device with respect to the indications for use, technological characteristics and use cases.

The main difference between the Subject and the Predicate device is a third digit version update to 2.0.2 to be compliant with the updated 3rd party Linac from Elekta with Integrated Gating (NEMA) interface) which resulted in the update of specifications and risk profile.

Topic/ Feature	Predicate Device	Subject Device
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.
Localization technique based on:	**ExacTrac Dynamic (ETD)** :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. **ExacTrac Dynamic Surface (ETDS)**: The camera detects both the patient surface and the patient thermal surface which together, can be used to track the patient geometries/ position. No X-Ray acquisition required.	**ExacTrac Dynamic (ETD)** :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. **ExacTrac Dynamic Surface (ETDS)**: The camera detects both the patient surface and the patient thermal surface which together, can be used to track the patient geometries/ position. No X-Ray acquisition required.

Topic/ Feature	Predicate Device	Subject Device
ETD Preparation and Review workflow	Preparation: • Import of RT Dicom • Define patient related settings • Define Template Review • Review of treatment • Approval of treatment	Preparation: • Import of RT Dicom • Define patient related settings • Define Template Review • Review of treatment • Approval of treatment
User Management setup	Done via Windows user management according to our instructions	Done via Windows user management according to our instructions
Deep Inspiration Breath-Hold (DIBH / Breath Hold (BH) workflow	**ExacTrac Dynamic:** Additionally, ExacTrac Dynamic 2.0 extended the deep inspiration breath hold to Breath-Hold (BH) functionality to treat breast and thorax cancer patients. **ExacTrac Dynamic Surface:** Workflow adaption to make a BH with external imaging for positioning and Surface Tracking Unit for monitoring	No changes

Topic/ Feature	Predicate Device	Subject Device
Surface Only workflow	**ExacTrac Dynamic Surface** The Surface Only workflow is provided as for ExacTrac Dynamic 1.1 with the following modifications: - Surface tracking during 3rd Party Positioning is provided to set the reference point for the treatment surface monitoring - Non-coplanar treatment angles are supported until a limited range (Only up to +-30°) - Prepositioning can be based on surface reference from previous treatment sessions The workflow can be executed on a HW platform not providing X-ray imaging components. For this setup a specific calibration function is introduced.	No changes
Patient Feedback Glasses	Patient Feedback Glasses provide an alternative solution to the Patient Feedback System to allow the patient to see the room monitor and on it the live respiratory status and the BH Gating Window.	Patient Feedback Glasses provide an alternative solution to the Patient Feedback System to allow the patient to see the room monitor and on it the live respiratory status and the BH Gating Window.
Gating Interface	Interface for Beam Hold and Beam Stop Based on the Standard NEMA Gating Interface (Applicable to Varian LINAC only)	Interface for Beam Hold and Beam Stop Based on the Standard NEMA Gating Interface (Applicable to Varian LINAC and Elekta EVO)

4. Performance Data

The Subject Device has been verified and validated according to Brainlab processes for product design and development. A high level explanation of the testing provided in this submission for the Subject Device is provided below.

Software verification

Software verification and validation testing has been conducted and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Device Software Functions". These include successful implementation of product specifications, incremental testing for different release candidates, testing of risk control measures, compatibility testing or cybersecurity tests. The documentation submitted is for enhanced level.

No additional bench testing was carried out for the Subject Device and the tests from the predicate device are still valid. Additionally, no clinical testing was required for the subject device.

5. Conclusion

The comparison of the Subject Device with the predicate device shows that it has similar functionality, intended use and technological characteristics as the predicate device. Based on the comparison to the predicate and the performance testing conducted, the Subject Device is considered substantially equivalent to the predicate device.