Brainlab AG
% Chiara Cunico
Manager - Regulatory Affairs, Quality Management
Olof-Palme-Str. 9
Munich, Bavaria 81829
GERMANY

July 22, 2021

Re: K211939
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: June 21, 2021
Received: June 23, 2021

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,

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

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)*
K211939

Device Name
ExacTrac Dynamic

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 deviations 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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K211939

510(k) Summary

July 22, 2021

General Information	
Manufacturer	Brainlab AG; Olof-Palme Str.9; 81829; Munich; Germany
Establishment Registration	8043933
Device Name	Accelerator, Linear, Medical
Trade Name	ExacTrac Dynamic
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	ExacTrac Dynamic; K201276

Contact Information	
Primary Contact	**Alternate Contact**
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1. Intended 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.

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 as a medical device consists of Hardware and Software. Together they are ExacTrac Dynamic.

ExacTrac Dynamic 1.0.3
UDI DI: 04056481142506
ExacTrac Dynamic has no variants.

ExacTrac Dynamic shall be installed in a treatment room within a hospital radiation therapy department.

Environmental conditions are as follows:

Humidity range: 30% - 70%

Ambient temperature: 16°C – 35°C

Atmospheric pressure: 800hPa – 1060hPa

ExacTrac uses X-ray images acquired with two X-ray tubes and two amorphous silicon detectors to compare the current patient position with the previously planned patient position, based on CT volumetric scans.

The current patient position is monitored using a surface monitoring system.

If necessary, the patient position is corrected using 3rd party patient treatment tables with or without pitch and roll correction possibilities.

Stereotactic radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) are a highly accurate form of the radiation therapy initially developed to treat small (benign or malignant) tumors and functional abnormalities of the brain.

During treatment a high dose of radiation is delivered within millimeter accuracy to the planned target volume (PTV) while minimizing the dose to the surrounding healthy tissue and organs at risk (OARs). For an accurate dose delivery a precise patient positioning is necessary and an eventual re-positioning of the patient in case of a patient movement during the treatment. The patient positioning system is based on two non-coplanar x-ray 2D image acquisition, that is accurately aligned to the volumetric planning CT (from the plan), the transformation matrix (of the 2D or 3D alignment) is sent to the treatment couch moving the patient to the planned iso-center of the treatment delivery system (Linac). During the treatment delivery the patient movement is monitored via a (3D) surface and a thermal information.

Additionally, an x-ray based position acquisition may be acquired and compared with the planned patient position. Quality assurance procedure are included to ensure a calibration of ExacTrac to itself and to the LINAC

3. Performance Data

Essential performance characteristics

As ExacTrac Dynamic does not provide any life-sustaining nor life-monitoring functionality and is not designed for the use in surgical or invasive procedures, a guaranteed availability (uptime) of its functionality is consequently not a safety requirement and therefore not part of the essential performance.

However, whenever these functions are available they must provide the specified performance.

The Essential Performance is summarized by

- Providing a patient position for accurate targeting
- Monitoring the patient position
- Holding the treatment beam in case of deviations during treatment monitoring (optional)

The Essential Performance in detail:

Positioning

i) Providing a shift for the patient support system compensating the deviation between patient position and planned position, where the shift is calculated with an accuracy of 1mm based on stereo x-ray images.

Positioning and Monitoring

ii) Display of an X-ray / DRR overlay and indicating a corresponding deviation between patient position and planned position, where the deviation is calculated with an accuracy of 1mm based on stereo x-ray images.

Monitoring

iii) Indicating a deviation exceeding a predefined tolerance between patient position and a reference position based on surface tracking with an accuracy of 1mm (during irradiation).
iv) Indicating a deviation exceeding a predefined tolerance between patient position and planned position based on stereo X-rays with an accuracy of 1mm (during irradiation).
v) Providing a “Beam hold” signal to the LINAC within 3 sec, if there is a deviation between patient position and reference position exceeding tolerance limits as adjusted by the user.

Not considered as Essential performance, but Basic safety to be evaluated regarding EMC testing as identified by risk management:

i) The x-ray settings transmitted to the x-ray generator must be submitted without any error or the error must be detected by ExacTrac.
ii) Noise on the trigger signal must not start kV image acquisition or start a fluoroscopic sequence.

Various verification and validation tests were carried out on the System, Hardware and Software as applicable.

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility testing

The subject device is not patient contacting. However, some components such as Verification and Calibration phantoms, ETD consoles and other parts of the device comes in contact with the user. Based on the present biological toxicological evaluation of existing data, the device is considered to meet the requirements of ISO 10993-1 and ISO 14971 for a device with limited contact duration (≤ 24 hours). As there is no patient contact for the device, it can be considered safe and suitable for its intended use.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Subject Device, as applicable. The device is in compliance with the below listed standards for safety and EMC.

IEC 60601-1:2012
IEC 60601-1-2:2014
IEC 60601-1-3:2013
IEC 60601-1-6:2014 / 62366 2015
IEC 60601-2-68:2014
CB 60601-1 (chapter 14) and CB 62304 - 104110180MIN-004

The Aim Standard 7351731 is not considered for ExacTrac Dynamic, as ExacTrac is installed in a Bunker which is radiation protected. Also, the natural skin barrier is intact during radiotherapy / Radiosurgery.

The Subject device has passed all the necessary tests and thereby is considered safe and effective for its intended use.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since the software is an accessory to a device with a 'Major' level of concern.

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 two bugs in the predicate device ExacTrac Dynamic 1.0.

The first bug came into effect for high dose treatments and influenced the detection of potential patient movement if the system's Automatic Beam Hold functionality was not used.

The second bug came into effect for tolerances setup in the patient settings can be exceeded and ExacTrac Dynamic does not give out a warning or displays a mandatory "Send Shift" in the GUI.

The bug fix did not require any change to the existing software architecture.
There was no change of intended use, technological characteristics or typical users.