September 16, 2026

Stabilix, LLC
Richard Westhoven
Co-Founder & CEO
4814 Manett St.
Dallas, Texas 75204

Re: K261865
Trade/Device Name: AerFrame™ Alignment Laser Box (LBV2)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: August 15, 2026
Received: August 17, 2026

Dear Richard Westhoven:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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Office of Product Evaluation and Quality
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261865

Device Name
AerFrame™ Alignment Laser Box (LBV2)

Indications for Use *(Describe)*

Indications for Use (AerFrame™ Alignment Laser Box)

The AerFrame™ Alignment Laser Box is indicated for use as an accessory to the AerFrame™ Patient Immobilization System to aid in patient positioning and alignment during photon-based radiotherapy setup. The Alignment Laser Box mounts to the AerFrame™ Coordinate Arch and projects visible laser reference points intended to align with marks on the patient's skin. The device is intended for use in professional healthcare facilities by trained clinical staff. The device is used only during treatment setup while the linear accelerator is in standby mode. Final patient alignment must be independently verified using image-guided radiotherapy (IGRT) prior to treatment delivery.

Intended Patient Population / Selection Criteria:

The AerFrame™ Alignment Laser Box is indicated for patients undergoing photon-based radiotherapy setup with the AerFrame™ Patient Immobilization System when supplemental visible laser reference points are used to support patient positioning and alignment. The device is intended only for use with the AerFrame™ Coordinate Arch and is not indicated for standalone use or for use with other immobilization or alignment systems.

Contraindications / Limitations:

The AerFrame™ Alignment Laser Box is not indicated for use as the sole method of final patient alignment. The device must not be used during treatment beam delivery or gantry movement and must be removed from the AerFrame assembly and treatment area before linear accelerator beam activation or gantry rotation. Final patient alignment must be performed using IGRT.

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 - K261865

AerFrame™ Alignment Laser Box

Prepared on: 2026-09-16

Contact Details	21 CFR 807.92(a)(1)

Applicant Name	Stabilix LLC
Applicant Address	4814 Manett St Dallas TX 75204 United States
Applicant Contact Telephone	8563045998
Applicant Contact	Mr. Richard Westhoven
Applicant Contact Email	richard.westhoven@stabilix.net

Device Name	21 CFR 807.92(a)(2)

Device Trade Name	AerFrame™ Alignment Laser Box (LBV2)
Common Name	Medical charged-particle radiation therapy system
Classification Name	Accessory to Accelerator, Linear, Medical
Regulation Number	892.5050
Product Code(s)	IYE

Legally Marketed Predicate Devices	21 CFR 807.92(a)(3)

Predicate #	**Predicate Trade Name (Primary Predicate is listed first)**	**Product Code**
K970291	Accessories to the Stereotactic Body Frame	IYE

Device Description Summary	21 CFR 807.92(a)(4)

Intended Use

The AerFrame Alignment Laser Box is intended to aid patient positioning and alignment during photon-based radiotherapy setup. It mounts to the AerFrame Coordinate Arch and projects visible laser reference points that align with marks on the patient's skin. The device is used only during treatment setup while the linear accelerator is in standby mode. Final patient alignment is independently verified using image-guided radiotherapy (IGRT).

Device Description

The Stabilix AerFrame™ Alignment Laser Box (LBV2) is a reusable, battery-powered, dual-beam visible laser patient positioning accessory designed for use with the AerFrame™ Patient Immobilization System in professional healthcare settings. The device is a non-contact setup aid that projects two visible red laser reference points onto patient skin marks during photon-based radiotherapy setup. The device does not contact the patient, contains no applied parts, and does not deliver therapy, acquire diagnostic images, or control any external equipment, including the linear accelerator (LINAC) or IGRT system.

The device includes the following primary elements:

- Aluminum device housing
- Two Class II visible red laser modules / apertures
- Factory-adjustable internal collimators that are not adjustable by the end user during clinical use
- Single 9V alkaline battery power source
- Push-button ON/OFF control
- Ball-nose spring plunger mechanical mounting interface for attachment to the AerFrame Coordinate Arch
- Sight window and reference line for coordinate positioning on the Coordinate Arch

The device is powered only by a 9V alkaline battery and has no mains input, external power input, software, firmware, microcontroller, printed circuit board (PCB), wireless connectivity, data storage, network interface, or patient-applied parts. The Alignment Laser Box is labeled MR UNSAFE and must be removed from the AerFrame assembly and treatment area before gantry movement or treatment beam activation.

Principle of Operation

During setup, the user mounts the Alignment Laser Box to the AerFrame Coordinate Arch crossbar using the bottom mounting groove and ball-nose spring plunger. Once engaged, the device can be positioned along the Coordinate Arch using the sight window and reference line to read the coordinate position from the Coordinate Arch markings. When activated by the ON/OFF push-button, the internal 9V alkaline battery powers two continuous-wave visible red laser modules. The modules project two 650 nm red laser reference points at the defined working distance to support alignment to patient skin marks or patient marking workflow. The device is used as a setup aid only; it is switched off and removed before gantry movement or treatment beam activation, and final patient alignment is independently verified using IGRT.

Intended Use/Indications for Use	21 CFR 807.92(a)(5)

Indications for Use (AerFrame™ Alignment Laser Box)

The AerFrame™ Alignment Laser Box is indicated for use as an accessory to the AerFrame™ Patient Immobilization System to aid in patient positioning and alignment during photon-based radiotherapy setup. The Alignment Laser Box mounts to the AerFrame™ Coordinate Arch and projects visible laser reference points intended to align with marks on the patient's skin. The device is intended for use in professional healthcare facilities by trained clinical staff. The device is used only during treatment setup while the linear

accelerator is in standby mode. Final patient alignment must be independently verified using image-guided radiotherapy (IGRT) prior to treatment delivery.

Intended Patient Population / Selection Criteria:

The AerFrame™ Alignment Laser Box is indicated for patients undergoing photon-based radiotherapy setup with the AerFrame™ Patient Immobilization System when supplemental visible laser reference points are used to support patient positioning and alignment. The device is intended only for use with the AerFrame™ Coordinate Arch and is not indicated for standalone use or for use with other immobilization or alignment systems.

Contraindications / Limitations:

The AerFrame™ Alignment Laser Box is not indicated for use as the sole method of final patient alignment. The device must not be used during treatment beam delivery or gantry movement and must be removed from the AerFrame assembly and treatment area before linear accelerator beam activation or gantry rotation. Final patient alignment must be performed using IGRT.

Indications for Use Comparison	21 CFR 807.92(a)(5)

The Stabilix AerFrame™ Alignment Laser Box (subject device) and the Elekta Accessories to the Stereotactic Body Frame (K970291) (predicate device) are both frame-associated accessories intended to support patient localization, positioning, and reproducible setup for extracranial radiotherapy workflows.

The predicate device is described as an accessory to the Stereotactic Body Frame designed for stereotactic diagnostic localization and stereotactic radiotherapy of extracranial targets. The AerFrame Alignment Laser Box performs the same general positioning-support function within the AerFrame Patient Immobilization System workflow by mounting to the AerFrame Coordinate Arch and projecting visible laser reference points that align with marks on the patient's skin during radiotherapy setup.

The AerFrame Alignment Laser Box intended use is narrower and more explicit than the predicate wording. The subject device is limited to photon-based radiotherapy setup, is used only while the linear accelerator is in standby mode, and requires final patient alignment to be independently verified using image-guided radiotherapy (IGRT). These differences do not constitute a new intended use because they do not change the fundamental clinical purpose of the device as a passive, non-contact, visible-laser positioning aid used before treatment delivery.

Like the predicate accessory, the AerFrame Alignment Laser Box does not deliver therapeutic radiation, does not acquire diagnostic images, does not control the linear accelerator, and does not independently determine final treatment position. Accordingly, the differences in wording between the subject device and predicate intended uses do not constitute a new intended use. Both devices are frame-associated accessories intended to support patient localization, positioning, and reproducible setup for extracranial radiotherapy.

Technological Comparison	21 CFR 807.92(a)(6)

The AerFrame™ Alignment Laser Box has similar technological characteristics to the Elekta Accessories to the Stereotactic Body Frame laser positioning accessory (K970291). Both devices are frame-mounted, battery-operated, visible-laser patient positioning accessories used during radiotherapy setup to project visible laser references onto patient skin marks. Both devices use an aluminum housing and a ball-nose plunger-style mechanical attachment to mount the laser accessory to the associated frame alignment structure: the AerFrame Coordinate Arch for the subject device and the Arc Ruler accessory for the predicate device.

The AerFrame Alignment Laser Box consists of an aluminum housing assembly containing two Class II visible red laser apertures. The device mounts to the AerFrame Coordinate Arch using a ball-nose spring

plunger and projects visible laser reference points to support alignment of the patient to externally marked setup references. The subject device is internally powered by a 9V alkaline battery, is user-controlled through ON/OFF operation, and is used only during treatment setup while the linear accelerator is in standby mode. Final patient alignment is independently verified using IGRT.

The subject device and predicate share the same basic principle of operation: battery-powered visible laser modules project non-therapeutic alignment references onto patient skin marks to aid reproducible setup before treatment delivery. Both are used only as positioning aids and do not deliver therapy, acquire images, control external equipment, or replace clinical verification of patient position. Differences such as current electrical safety and EMC evaluation, MR UNSAFE labeling, defined essential performance criteria, and explicit workflow controls do not alter the device's basic operating principle. The performance evidence addressing these differences demonstrates substantial equivalence.

Comparison of Technological Characteristics

Characteristic	Stabilix AerFrame™ Alignment Laser Box (Subject Device)	Elekta K970291 Laser Positioning Accessory (Predicate)
Intended Use	The AerFrame Alignment Laser Box is intended to aid patient positioning and alignment during photon-based radiotherapy setup. It mounts to the AerFrame Coordinate Arch and projects visible laser reference points that align with marks on the patient's skin. The device is used only during treatment setup while the linear accelerator is in standby mode. Final patient alignment is independently verified using image-guided radiotherapy (IGRT).	The Accessories to the Stereotactic Body Frame is a device designed for stereotactic diagnostic localization and stereotactic radiotherapy of extracranial targets.
Primary Function	Projects visible laser reference points to aid setup alignment to patient skin marks.	Projects visible laser reference points to aid patient repositioning to skin marks.
Key Components (scope of 510(k))	CNC-milled aluminum housing, two Class II visible red laser modules, ON/OFF switch, battery compartment, 9V alkaline battery, DC-DC voltage converter, factory-set collimators, sight window/reference line, and mechanical mounting interface.	Frame-mounted laser positioning accessory with aluminum housing, visible laser modules, battery power source, user control, and mechanical mounting interface; cleared with the Elekta stereotactic body frame accessory set.
Principle of Operation	Battery-powered visible laser modules project non-therapeutic alignment points onto patient skin marks during setup. Device is removed before beam activation or gantry rotation.	Visible laser alignment accessory projects reference points for setup/repositioning before treatment delivery.
Mounting / Host Interface	Mounts to the AerFrame Coordinate Arch crossbar using a ball-nose spring plunger; intended only for use with AerFrame.	Mounted to the Arc Ruler accessory to the Elekta Stereotactic Body Frame using a ball-nose plunger.
Laser Characteristics	Two red visible laser beams, 650 nm, <1 mW per beam; Class II per IEC 60825-1 Ed. 3.0 (2014).	Visible laser positioning system; specific wavelength/output details not specified in available clearance information.
Power Source	Internally powered by one 9V alkaline battery (IEC 6LR61) with 9V-to-5V DC-DC conversion.	Battery-operated visible laser positioning accessory. Specific battery type is not specified in the available clearance information.
Electrical / EMC Characteristics	Evaluated to IEC 60601-1 Ed. 3.2 and IEC 60601-1-2 Ed. 4.1; enclosure-port-only device; CISPR 11 Group 1 Class A.	Cleared under standards applicable at the time of clearance in 1997.
Software / Wireless	None. No software, firmware, microcontroller, PCB, wireless function, data storage, or network connection.	No software-related functionality identified for the predicate frame-mounted laser positioning function.
Patient Contact / Applied Parts	No patient contact and no applied parts.	No patient contact for the laser positioning accessory.
MRI Workflow Considerations	MR UNSAFE; labeling instructs users not to bring the device into the MRI environment.	MR status not specified in available clearance information.

Essential Performance	Maintains optical output <=1 mW per beam and alignment within +/-2 mm at the defined working distance during applicable testing.	Essential performance not defined in available clearance information.
Sterility / Reprocessing	Reusable, non-sterile, non-contact accessory; cleaning/disinfection per IFU.	Reusable accessory; reprocessing per predicate labeling/clinical workflow.

Non-Clinical and/or Clinical Tests Summary & Conclusions	21 CFR 807.92(b)

Nonclinical performance testing was conducted to support the substantial equivalence determination for the Stabilix AerFrame™ Alignment Laser Box (LBV2). Testing included (1) electrical safety testing to evaluate basic safety for the internally powered device configuration, (2) electromagnetic compatibility testing and FDA common electromagnetic emitter evaluation, (3) bench testing of laser output power, beam alignment accuracy, mounting-use performance, battery life, and environmental suitability, and (4) human factors/usability validation to verify that labeling and the Instructions for Use (IFU) support correct use by intended professional users without unacceptable use-related risk. No clinical testing was submitted, referenced, or relied upon to support substantial equivalence.

1. Electrical Safety

Electrical safety testing was performed to IEC 60601-1 Ed. 3.2 and ANSI/AAMI ES60601-1:2005/A2:2021 for the final Alignment Laser Box configuration. The device was evaluated as portable, internally powered ME equipment with one 9V alkaline battery, continuous operation, no applied parts, no patient-coupled connections, no mains connection, and no external signal/data ports. All applicable IEC 60601-1 and ANSI/AAMI ES60601-1 tests passed. These electrical safety test results contribute to the performance evidence that demonstrates substantial equivalence.

2. Electromagnetic Compatibility and Common EM Emitters

Electromagnetic compatibility testing was performed on the final finished AerFrame Alignment Laser Box to IEC 60601-1-2:2014+A1:2020 and FDA's June 2022 guidance, Electromagnetic Compatibility (EMC) of Medical Devices. The Alignment Laser Box was evaluated as an internally powered, enclosure-port-only device intended for use in a professional healthcare facility environment.

The Alignment Laser Box was EMC tested as a stand-alone accessory, separately from a linear accelerator. No specific linear accelerator manufacturer or model was included in the EMC test configuration. The tested device was operated with the lasers ON, and essential performance was monitored throughout applicable immunity exposures using optical monitoring of each laser beam through an aperture-based alignment fixture.

Radiated emissions testing was performed to CISPR 11 Group 1, Class A limits over 30 MHz to 1000 MHz at a 3.0 m test distance. The device passed radiated emissions testing, with no measured points within 20 dB of the applicable limit. Conducted emissions, harmonic emissions, and voltage fluctuations/flicker were not applicable because the device is internally battery powered and has no mains or external DC connection.

Applicable immunity testing included:

- Electrostatic discharge: ±8 kV contact discharge. Air discharge was not applicable because no exposed non-conductive discharge locations were identified on the all-metal device enclosure.
- Radiated RF immunity: 10 V/m from 80 MHz to 2700 MHz, 80% AM at 1 kHz.
- RF wireless communications proximity fields: 27 V/m at 385 MHz; 28 V/m at 450, 810, 870, 930, 1720, 1845, 1970, and 2450 MHz; and 9 V/m at 710, 745, 780, 5240, 5500, and 5785 MHz, applied at a 0.3 m test distance in accordance with the applicable IEC 60601-1-2 Table 9 test conditions.
- Power-frequency magnetic fields: 30 A/m at 50 Hz and 60 Hz.

- Conducted RF immunity, electrical fast transient/burst, surge, and voltage dips/interruptions were not applicable because the Alignment Laser Box has no AC mains connection, external DC connection, cables, or external signal/data ports.

Supplemental immunity testing to common electromagnetic emitters was also performed in accordance with FDA EMC guidance and included electronic article surveillance systems, metal detectors, diathermy equipment, electrosurgical units, medical/dental X-ray equipment, NFC, wireless power transfer, and 5G cellular sources. The device passed the applicable common-emitter evaluations without observed degradation of essential performance.

Essential performance was monitored during immunity testing. Laser optical output remained at or below 1.00 mW per beam, and laser alignment remained within ±2.0 mm at the 275 mm working distance during the applicable electromagnetic exposures.

Labeling instructs users to maintain at least 30 cm (12 inches) separation between portable RF communications equipment and the Alignment Laser Box. This separation distance is based on the IEC 60601-1-2 Table 9 proximity-field levels of 9 to 28 V/m applied at a 0.3 m test distance. Labeling specifies no additional separation distance for other RF sources. The Alignment Laser Box was evaluated for radiated RF immunity at 10 V/m from 80 MHz to 2700 MHz, which exceeds the 3 V/m test level specified in IEC 60601-1-2 for the professional healthcare facility environment. Because EMC testing was performed separately from the linear accelerator, a specific minimum separation distance between the Alignment Laser Box and a LINAC was not established by the testing. When the Alignment Laser Box is introduced for use with a new or different accelerator model or materially different treatment-room configuration, the responsible facility is instructed to verify normal operation in the intended setup position with the accelerator in standby mode and the treatment beam off. If abnormal operation or suspected electromagnetic interference is observed, the device must not be used for patient setup until the source of interference is identified and normal operation is verified. The Alignment Laser Box is removed before beam activation or gantry movement, and final patient alignment is independently verified using IGRT.

These EMC and common electromagnetic emitter test results contribute to the performance evidence that demonstrates substantial equivalence.

3. Laser Output and Alignment Performance

Laser output and alignment performance testing verified the device's defined essential performance criteria. Each visible red laser beam was required to remain at or below 1.00 mW per beam, consistent with Class II laser output under IEC 60825-1 Ed. 3.0 (2014), and each beam was required to remain aligned within +/-2.0 mm of the designated alignment target at the 275 mm working distance. Optical power and beam alignment were monitored during EMC immunity testing using two Thorlabs S121C sensors mounted behind 6.5 mm target apertures on the Stabilix alignment jig at the intended working distance.

All optical power readings remained within the acceptable range of 0.01 mW to 1.00 mW per beam. No beam exceeded the 1.00 mW Class II limit, and both beams maintained the alignment proxy criteria supporting +/-2.0 mm alignment accuracy at the intended working distance. These results support the device's intended function as a visible laser setup aid and demonstrate that laser output and alignment performance are maintained during applicable testing.

4. Mounting, Battery Life, and Environmental Performance

Mounting mechanism and device mechanical-integrity evidence support the intended use of the Alignment Laser Box with the AerFrame Coordinate Arch. The mounting interface uses a bottom mounting groove and ball-nose spring plunger to provide tactile engagement to the Coordinate Arch. Human factors/use-related evaluation confirmed that intended users could mount, position, verify engagement, switch on, switch off, and remove the device during the setup workflow. No detachment events, loose-attachment events, device drops, or unresolved safety-related use problems were reported for the in-scope Alignment Laser Box tasks.

Battery-life and environmental performance evaluations support continued operation within the specified clinical use environment. The device is powered by a user-replaceable 9V alkaline battery and includes IFU controls for battery replacement, inspection, cleaning/disinfection, storage, and removal from service if damage, malfunction, abnormal wear, or degraded labeling is observed. The device is specified for

professional healthcare use within defined operating and storage conditions and is labeled IPX0 and MR UNSAFE.

5. Human Factors / Usability Validation Testing (HFE)

Human factors/usability validation testing was conducted to verify that the final device labeling and IFU support correct setup and safe use by intended clinical users in a representative professional healthcare environment. The in-scope LBV2 tasks included pre-use inspection, mounting to the Coordinate Arch, positioning using the sight window/reference line and Coordinate Arch markings, activation, use of the visible laser reference points during setup, switching the device off, removing the device before gantry rotation or beam activation, battery-related handling, cleaning/disinfection comprehension, and recognition of the MR UNSAFE designation.

The evaluation demonstrated that intended professional users could complete the critical setup and safety tasks using the provided labeling and IFU, with no critical use errors, close calls, detachment events, or unresolved safety-related use problems for the in-scope Alignment Laser Box tasks. The HFE evidence supports the conclusion that the device labeling and IFU provide adequate use-related risk controls for the intended users and use environment.

6. Clinical Testing

Not Applicable. No clinical testing was submitted, referenced, or relied upon to support a determination of substantial equivalence for this 510(k); substantial equivalence is supported by nonclinical bench testing, electrical safety testing, electromagnetic compatibility testing, laser output/alignment performance testing, risk management, labeling, and human factors/usability validation testing.

7. Conclusion

The information provided in this 510(k) demonstrates substantial equivalence of the AerFrame™ Alignment Laser Box (LBV2) to the legally marketed predicate, the Elekta Accessories to the Stereotactic Body Frame laser positioning accessory cleared under K970291. The subject device has the same fundamental intended use as a frame-mounted visible-laser patient positioning aid for radiotherapy setup and employs similar visible-laser alignment technology. The subject device and predicate share key technological characteristics, including battery operation, aluminum housing construction, visible laser projection, non-contact setup use, and ball-nose plunger-style mounting to the associated frame alignment structure.

Nonclinical performance testing demonstrated that the subject device met the applicable acceptance criteria. Electrical safety testing complied with IEC 60601-1 and ANSI/AAMI ES60601-1; EMC and common-emitter testing passed; laser output remained within the Class II limit and beam alignment remained within the specified tolerance; and mounting-use, battery/environmental, and human factors evaluations supported the intended setup workflow and labeling. These results address the technological differences from the predicate and, together with the intended-use and technological-characteristics comparison, demonstrate substantial equivalence of the AerFrame™ Alignment Laser Box (LBV2) to the Elekta predicate cleared under K970291.