



May 8, 2026

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

Re: K260792

Trade/Device Name: AerFrame Patient Immobilization System (AFPIS)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: March 7, 2026
Received: March 11, 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,

A handwritten signature in black ink, reading "Lora D. Weidner". The signature is fluid and cursive. A large, light blue "FDA" watermark is visible in the background behind the signature.

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

510(k) Number (if known)

K260792

Device Name

AerFrame Patient Immobilization System (AFPIS)

Indications for Use (Describe)

Indications for Use (AerFrame™ Patient Immobilization System)

The AerFrame™ Patient Immobilization System is indicated for use to aid in patient positioning and immobilization during diagnostic imaging procedures (e.g., CT and MRI) and photon-based radiotherapy. When used for radiotherapy, the system is indicated for use only in conjunction with image-guided radiotherapy (IGRT) for final patient alignment. The AerFrame system is intended for use in professional healthcare facilities by trained clinical staff.

Intended Patient Population / Selection Criteria:

The AerFrame system is indicated for patients who require immobilization to support repeatable positioning during CT/MRI imaging and photon-based radiotherapy workflows and who can be safely accommodated within the AerFrame and the required vacuum bag immobilization system. The system is intended for use with a compatible vacuum bag system and is not indicated for use without a vacuum bag. Maximum patient weight is 300 lb (136 kg).

Contraindications / Limitations:

No specific contraindications. The AerFrame system is not indicated for patients who exceed the maximum patient weight limit (300 lb / 136 kg) or when use of the required vacuum bag is not possible. When used for radiotherapy, the AerFrame system is not indicated for use as the sole method of final patient alignment; IGRT must be used for final alignment.

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- K260792

Prepared on: 2026-04-02

Contact Details	21 CFR 807.92(a)(1)
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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)
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Device Trade Name	AerFrame Patient Immobilization System (AFPIS)
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)
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Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K960338	Stereotactic Body Frame	IYE

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

AerFrame is intended for immobilizing patients undergoing diagnostic imaging procedures (e.g., CT and MRI) and photon-based radiotherapy. When used for radiotherapy, the system must be used in conjunction with image-guided radiotherapy (IGRT) for final patient alignment.

Device Description

The Stabilix AerFrame™ Patient Immobilization System is a reusable, non-powered patient immobilization system intended to aid in patient positioning and immobilization during diagnostic imaging (e.g., CT and MRI) and photon-based radiotherapy in professional healthcare settings.

- AerFrame Base with Integrated Side Rails
- Coordinate arch
- EPS Foam Headrest
- Abdominal Compression Assembly

The AerFrame base includes embedded fiducial markers visible on CT and MRI. These fiducials are provided only as optional visual references; they are not required for use and must not be used for target-coordinate determination or final patient alignment. Final patient alignment is performed using IGRT.

Principle of Operation

The AerFrame system provides a rigid support structure and repeatable setup references to support consistent patient immobilization during diagnostic imaging and radiotherapy simulation and treatment. During simulation, the patient is positioned using a third-party vacuum bag placed within the AerFrame base and formed to the patient anatomy per the vacuum bag manufacturer's instructions. For each treatment session or imaging session, the same patient-specific vacuum bag configuration is used with the AerFrame base. Integrated side rails and measurement markings provide setup references and support consistent placement of the optional abdominal compression assembly when used. When prescribed, the abdominal compression assembly applies controlled pressure to the patient's abdomen via an adjustable screw and compression plate to support respiratory motion management during setup. MRI safety information and labeling for AerFrame components and accessories are provided in the IFU.

Intended Use/Indications for Use	21 CFR 807.92(a)(5)
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Indications for Use (AerFrame™ Patient Immobilization System)

The AerFrame™ Patient Immobilization System is indicated for use to aid in patient positioning and immobilization during diagnostic imaging procedures (e.g., CT and MRI) and photon-based radiotherapy. When used for radiotherapy, the system is indicated for use only in conjunction with image-guided radiotherapy (IGRT) for final patient alignment. The AerFrame system is intended for use in professional healthcare facilities by trained clinical staff.

Intended Patient Population / Selection Criteria:

The AerFrame system is indicated for patients who require immobilization to support repeatable positioning during CT/MRI imaging and photon-based radiotherapy workflows and who can be safely accommodated within the AerFrame and the required vacuum bag immobilization system. The system is intended for use with a compatible vacuum bag system and is not indicated for use without a vacuum bag. Maximum patient weight is 300 lb (136 kg).

Contraindications / Limitations:

No specific contraindications. The AerFrame system is not indicated for patients who exceed the maximum patient weight limit (300 lb / 136 kg) or when use of the required vacuum bag is not possible. When used for radiotherapy, the AerFrame system is not indicated for use as the sole method of final patient alignment; IGRT must be used for final alignment.

Indications for Use Comparison	21 CFR 807.92(a)(5)
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The Stabilix AerFrame™ Patient Immobilization System (subject device) and the Elekta Stereotactic Body Frame (K960338) (predicate) are both intended to immobilize patients to support accurate setup and targeting during external beam radiotherapy of extracranial sites.

The AerFrame intended use statement specifies that the device is intended for photon-based radiotherapy and that it must be used in conjunction with image-guided radiotherapy (IGRT) for final patient alignment. These differences do not constitute a new intended use because they do not change the fundamental therapeutic use of the device as a passive patient immobilization accessory. The AerFrame does not deliver energy, does not control the radiation source, and does not introduce a new diagnostic or therapeutic modality.

Limiting the indication to photon-based radiotherapy narrows the scope of use relative to broader external beam applications and does not change the fundamental intended use of the device. Requiring IGRT for final alignment reflects current standard clinical practice and functions as an additional workflow control to confirm patient positioning prior to treatment, without changing the underlying clinical purpose (immobilization) or the basic mechanism of action. As labeled, the AerFrame provides immobilization and supports coarse setup, while IGRT provides the final position verification, consistent with contemporary radiotherapy workflows. These differences demonstrate substantial equivalence.

Technological Comparison	21 CFR 807.92(a)(6)
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The AerFrame™ Patient Immobilization System has similar technological characteristics to the Elekta Stereotactic Body Frame (K960338). Both devices are non-invasive, reusable, non-sterile, passive mechanical immobilization systems intended for use by trained clinical staff to support reproducible patient setup for radiotherapy.

The AerFrame consists of a rigid cradle/frame base with integrated side rails and ruler markings, a removable coordinate arch accessory used during setup for coarse alignment relative to in-room lasers, and an abdominal compression assembly used when clinically indicated to reduce respiratory motion. The system is used with a compatible vacuum bag/cushion interface (not provided) to conform to patient anatomy. The AerFrame is not powered, contains no software, and within this submission does not include the alignment laser box.

Like the predicate, the AerFrame is not mechanically indexed or fixed to the treatment couch; it is positioned on the tabletop during setup and stabilized by patient weight, with final position confirmation performed per labeled workflow. The AerFrame uses radiolucent structural materials intended to minimize interference with imaging and photon beam delivery. A labeled maximum patient weight (300 lb / 136 kg) is defined for the AerFrame and is supported by non-clinical verification testing included elsewhere in the submission.

Any differences from the predicate (e.g., explicit IGRT workflow requirement, defined weight limit, and specific material selections) do not alter the device's basic operating principle of passive immobilization and demonstrate substantial equivalence.

Comparison of Technological Characteristics

Characteristic	Stabilix AerFrame™ (Subject Device)	Elekta SBF (Predicate, K960338)
Intended Use	AerFrame is intended for immobilizing patients undergoing diagnostic imaging procedures (e.g., CT and MRI) and photon-based radiotherapy. When used for radiotherapy, the system must be used in conjunction with image-guided radiotherapy (IGRT) for final patient alignment.	The stereotactic body frame is a device designed for stereotactic diagnostic localization and stereotactic radiotherapy of extracranial targets.
Primary Function	Passive patient immobilization and reproducible setup; optional abdominal compression to reduce respiratory motion.	Passive patient immobilization and reproducible setup; optional abdominal/diaphragm compression to reduce respiratory motion.
Key Components (scope of 510(k))	Rigid cradle/frame base with side rails and ruler markings; headrest; coordinate arch accessory; abdominal compression assembly.	Rigid body frame/cradle with rails/scales; abdominal compression accessory; localization/alignment accessory (e.g., arc/marker) as applicable.
Principle of Operation	Non-invasive mechanical immobilization (frame + vacuum bag) with optional abdominal compression; coarse alignment supported using in-room lasers and the removable coordinate arch; final alignment verified using IGRT.	Non-invasive mechanical immobilization (frame + cushion/vacuum bag) with optional compression; alignment verified per clinical workflow.
Materials (general)	Radiolucent composite structure designed to minimize attenuation and imaging artifacts; materials selected for repeated use and cleaning/disinfection.	Radiolucent frame structure designed to minimize imaging artifacts and attenuation; materials suitable for repeated clinical use.
Radiopaque Fiducials	Integrated passive fiducials filled with epoxy resin arranged in a defined zig-zag pattern along the base; used as visual reference markers on CT/MRI to support setup	Included frame reference/marker features used for localization and setup within the clinical workflow;

	and image registration. Final alignment performed using IGRT. Not used for stereotactic coordinate determination.	final alignment and verification performed per site practice.
Weight Capacity / Structural Integrity	Maximum patient weight: 300 lb (136 kg). Verified by static and dynamic mechanical testing with defined acceptance criteria.	Supports typical adult patients; constrained by device geometry and couch limits; extensive clinical use history.
Couch Attachment / Indexing	Not fixed or indexed to the treatment couch; positioned using in-room lasers and rail ruler markings; patient weight stabilizes frame; verified by IGRT.	Not fixed or indexed to the treatment couch; positioned using room references; patient weight stabilizes frame.
Radiation Attenuation	Radiolucent composite structure; bench testing performed using clinically relevant photon energies and beam angles to confirm beam transmission/attenuation meets protocol acceptance criteria, including worst-case attenuation $\leq 3\%$.	Radiolucent frame structure designed to minimize attenuation and imaging artifacts; clinically used with acceptable beam transmission.
MRI Workflow Considerations	Abdominal compression arch available in MR-SAFE variant; labeling addresses MR status and removal of non-compatible components prior to MRI, as applicable.	Designed to support imaging workflows; MRI use dependent on configuration and accessories.
Electrical / Software	None (within scope of this submission).	None inherent to the primary frame function.
Sterility / Reprocessing	Reusable, non-sterile; cleaned/disinfected per IFU.	Reusable, non-sterile; cleaned/disinfected per labeling/IFU.

Non-Clinical and/or Clinical Tests Summary & Conclusions	21 CFR 807.92(b)
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Nonclinical performance testing was conducted to support the substantial equivalence determination for the Stabilix AerFrame™ Patient Immobilization System. Testing included (1) mechanical load and durability bench testing to evaluate structural integrity under anticipated and worst-case use conditions up to the maximum claimed patient weight, (2) real world and simulated radiation attenuation performance testing to confirm negligible dosimetric impact during photon-based radiotherapy, and (3) human factors validation testing to verify that the labeling and Instructions for Use (IFU) support correct use by intended users without unacceptable use-related risk. The AerFrame Pre-Submission Testing Report is included in this section as the detailed test report supporting the summary below.

1. Mechanical Bench Testing (Structural Performance / Durability)

Mechanical testing was performed to verify mechanical integrity and structural performance under normal use conditions and to support the claimed maximum patient weight of 300 lb. Acceptance criteria for frame deflection were defined based on compression arch engagement requirements, with a maximum allowable deflection of 5 mm to maintain proper engagement with the frame rails during use.

Weight-Dependent Deformation (Static Load): Evenly distributed loading was applied in 50 lb increments up to 300 lb. Deflection was measured using digital calipers (0.01 mm resolution) at critical points along the frame sides. No visible cracks, delamination, or component detachment were observed at any load level; maximum observed deflection remained <1 mm at 300 lb, well below the 5 mm acceptance criterion.

Time-Dependent Deformation (Sustained Load / Creep): A sustained 300 lb distributed load was applied for 1 hour to represent a complete treatment duration and evaluate creep/stress relaxation effects. Deflection remained well below the 5 mm acceptance criterion throughout the test duration with no evidence of progressive deformation/creep or structural degradation.

Cyclical Loading (Fatigue / Repeated Use): A 300 lb distributed load was repeatedly applied and removed for 1,000 cycles (approximately 10 cycles/min) with deflection measured at predefined intervals and visual inspections throughout. Structural response remained within acceptable limits with no progressive fatigue effects and no cracks or delamination observed after completion of testing.

Patient Loading Test (Edge Loading During Transfer): A 100 lb load was applied to the top edges of the frame sides to simulate patient transfer/positioning forces. All edge deflection measurements remained <1 mm, with complete recovery after load removal and no visible damage observed.

Impact Testing (Worst-Case Transfer Event): A 50 lb weight was dropped from 16 inches onto the frame base and repeated 10 times to simulate repeated impact scenarios during uncontrolled patient descent/transfer. The frame absorbed impact energy without immediate or permanent deformation or structural damage; visual inspection revealed no cracks or delamination.

2. Radiation Attenuation Performance Testing (Dose Impact)

Radiation attenuation testing was performed to quantify attenuation characteristics and confirm minimal impact on radiation therapy delivery. The acceptance criterion was based on the AAPM TG-215 negligible attenuation threshold of <3% attenuation (Transmission Factor ≥ 0.97).

Computational Attenuation Testing: Three devices were CT scanned with a pelvic phantom in a vacuum bag and imported into Eclipse TPS (Varian) using Acuros XB for dose calculation at 6 MV using clinically relevant IMRT/SBRT plan types (including multi-field and VMAT techniques). 6 MV was chosen as a worst case scenario because it is commonly the lowest energy provided on clinical linacs and will have higher attenuation compared to higher beam energies. In all scenarios, attenuation attributable to the frame was <3%, and in most cases <2%.

Physical Attenuation Measurements (Ion Chamber): Ion chamber measurements were performed with the chamber inserted into a solid water phantom positioned in the frame at 100 cm SAD. Various beam energies and angles were evaluated; 6 MV at 62.1° gantry angle was treated as worst case due to beam traversal through the solid plastic rail component. Transmission factors were calculated as the ratio of dose with the device present to dose without the device present, using three measurements per configuration. Measured transmission factors exceeded 0.97 (<3% attenuation) across conditions, except the worst-case geometry, where it was 0.96 (4% attenuation).

3. Human Factors / Usability Validation Testing (HFE)

Human factors validation testing was conducted to verify that the labeling and IFU enable correct patient setup and to identify any design or instruction shortcomings that could lead to use errors.

Testing was performed in a simulated clinical environment including a treatment couch and in-room alignment lasers. Five licensed radiation therapists with varying experience levels participated; each performed a complete setup scenario using only the IFU (no additional training) while being observed and recorded for analysis. Critical tasks included patient setup and vacuum bag immobilization, attachment/alignment of the coordinate arch, attachment/operation of the laser box and alignment to patient marks, and use of the abdominal compression assembly where applicable. Human factors activities were conducted in alignment with FDA human factors guidance (2016) and IEC 62366-1 usability engineering principles as described in the testing report materials.

4. 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 (mechanical performance and radiation attenuation) and human factors/usability validation testing.

5. Conclusion

Bench and usability testing demonstrate substantial equivalence of the AerFrame™ Patient Immobilization System to the legally marketed predicate device. Mechanical bench testing demonstrated structural integrity and durability under anticipated and worst-case loading conditions up to the maximum claimed patient weight, with deflections remaining well below acceptance criteria and with no evidence of fatigue, cracking, delamination, or structural degradation during static, sustained, cyclic, edge-loading, and impact evaluations. Radiation attenuation testing (computational and ion chamber measurement) demonstrated negligible dosimetric impact for multi-beam plans (<3% attenuation; transmission factors ≥ 0.97), supporting compatibility with photon-based radiotherapy workflows and modern treatment planning and adaptive radiotherapy systems. Human factors validation demonstrated that intended users (licensed radiation therapists) can perform critical setup and use tasks using the provided labeling and IFU in a simulated clinical environment. Collectively, these performance data demonstrate substantial equivalence for the AerFrame™ Patient Immobilization System.