May 22, 2026

Pulmera, Inc
% Kyle O'Sullivan
President
Innovative Product Advocates
803 7th St. NW,
WASHINGTON DC, DC 20001

Re: K252735
Trade/Device Name: C-beam
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAK
Dated: April 24, 2026
Received: April 24, 2026

Dear Kyle O'Sullivan:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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)*
K252735

Device Name
C-Beam

Indications for Use *(Describe)*
The C-Beam device is intended to provide 3D medical imaging of patients during orthopedic, neurological, intra-operative surgical procedures and where the clinician benefits from 3D visualization of complex anatomical structures, such as but not limited to those of high contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, and where digital image and C-arm positioning data is required for Computer-Assisted Surgery procedures. The visualization of such anatomical structures assists the clinician in the clinical outcome.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Basic Information

Manufacturer: Pulmera, Inc
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Date prepared: 04/22/2026

Subject Device Name and Classification

Trade Name: C-Beam
Model Number: 1.0
Classification Name: Image-intensified fluoroscopic X-ray System
Common Name: Interventional Fluoroscopic X-Ray System
Classification Panel: Radiology
Regulation Number: 21 CFR §892.1650
Device Class: Class II
Product Codes: OWB
Subsequent Product Codes: JAK

Primary Predicate Device

Trade/Device Name: Ziehm Vision RFD 3D
Manufacturer: Ziehm Imaging GmbH
510(k) Clearance K243303
Clearance Date 01/21/2025
Regulation Name: Image-intensified fluoroscopic X-ray System
Classification Panel: Radiology
Regulation Number: 21 CFR §892.1650
Device Class: Class II
Product Code: OWB

Reference Device

Trade Name:	ILLUMISITE Platform
Manufacturer:	Covidien LLC
510(k) Clearance	K191394
Clearance Date	08/07/2019
Regulation Name:	Computed Tomography x-ray system
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Intended Use/ Indications for use

The C-Beam device is intended to provide 3D medical imaging of patients during orthopedic, neurological, intra-operative surgical procedures and where the clinician benefits from 3D visualization of complex anatomical structures, such as but not limited to those of high contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, and where digital image and C-arm positioning data is required for Computer-Assisted Surgery procedures. The visualization of such anatomical structures assists the clinician in the clinical outcome.

Device description

The Pulmera C-Beam 1.0 is a device that is used with the cleared GE OEC Elite 31cm CFD C-arm system (most recently K192819). When installed on a GE OEC Elite C-arm, the C-Beam system converts 2D fluoroscopic images obtained from the C-arm into 3D CT-like tomographic image volumes of high contrast objects for intraoperative use.

The C-Beam system consists of a workstation/computer and an inertial measurement unit (IMU) that attaches to the C-arm via a dedicated IMU housing. The IMU housing is permanently affixed to the C-arm, while the IMU itself may be removed from the housing when not in use.

During use, the C-Beam system collects a series of 2D fluoroscopic images as the C-arm is manually rotated around the patient and reconstructs those images into 3D CT-like slices. The resulting 3D images are intended for intraoperative visualization to support surgical planning, procedural assessment, and surgical guidance.

The C-Beam system provides supplemental intraoperative 3D visualization of high-contrast anatomical structures. It is not intended to replace diagnostic imaging modalities and is not intended for primary diagnostic interpretation. C-Beam should not replace standard-of-care imaging practices.

Summary of Characteristics Compared to Predicate Device(s)

- The subject device has the same concept as a subset of functionality of the predicate, namely taking 2D images and reconstructing 3D images for high contrast objects
- The subject device is only the IMU (to measure the C-arm position) and the computer/software to create 3D images from the 2D x-rays from the "host" device and provide a GUI to guide the operator; the C-Beam does not itself deliver x-rays
- The host device is the GE OEC Elite (31 cm CFD) most recently cleared as K192819
- The IFU for the subject device is narrower than the predicate
- The subject device utilizes manual rotation of the GE C-arm instead of motorized rotation used by the Ziehm predicate device. The reference device (K191394 Illumisite) has manual rotation and is used in operating rooms.

Substantial Equivalence Comparison

Characteristics & Features	Subject Device C-Beam V1.0	Predicate Device Ziehm Vision RFD 3D (K243303)	Reference Device Covidien Illumisite (K191394)	Comparison to Subject device
Regulation	21 CFR 892.1650	21 CFR 892.1650	21 CFR 892.1750	Subject device same as predicate
Product Code	OWB	OWB	JAK	Subject device same as predicate
Class	II	II	II	Subject device same as predicate
Indications for use	The C-Beam system is intended to provide 3D medical imaging of patients during orthopedic, neurological, intra-operative surgical procedures and where the clinician benefits from 3D visualization of complex anatomical structures, such as but not limited to high-contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, and where digital image and C-arm positioning data is	The Ziehm Vision RFD 3D system is intended for use in providing both 2D and 3D pulsed and continuous fluoroscopic medical imaging for adult and pediatric populations. The device provides 2D medical imaging for fluoroscopy, digital subtraction, and acquisition of cine loops during diagnostic interventional and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography,	Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.	The subject device Indications for Use is a subset of the predicate device indications. The subject device only provides 3D images; is only used for a subset of the indicated population; and is limited to high contrast anatomical structures.

Characteristics & Features	Subject Device C-Beam V1.0	Predicate Device Ziehm Vision RFD 3D (K243303)	Reference Device Covidien Illumisite (K191394)	Comparison to Subject device
	required for Computer-Assisted Surgery procedures. The visualization of such anatomical structures assists the clinician in the clinical outcome.	electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumbar regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for Computer-Assisted Surgery procedures. The device is also intended to provide 3D medical imaging of patients during orthopedic, neurological, intra-operative surgical procedures and where the clinician benefits from 3D visualization of complex anatomical structures, such as but not limited to those of high contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, and where digital image and C-arm positioning data is required for Computer-Assisted Surgery procedures. The visualization of such anatomical structures assists the clinician in the clinical outcome.		

Characteristics & Features	Subject Device C-Beam V1.0	Predicate Device Ziehm Vision RFD 3D (K243303)	Reference Device Covidien Illumisite (K191394)	Comparison to Subject device
		This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use in any MRI environments.		
Target population	Adult population	All adult and pediatric populations	Adult population	Subject device contains a subset of the predicate device population
Target anatomy	High contrast bony anatomy	….complex anatomical structures, such as but not limited to those of high contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, ….	Lung, airways and tracheobronchial tree	Subject device contains a subset of the predicate device anatomy
C-arm X-ray detector type	31 cm x 31 cm Flat Panel Detector*	30 cm x 30 cm Flat Panel Detector	-	Similar to predicate
C-arm gantry	Offset/ non-isocentric*	Offset/ non-isocentric	Offset/ non-isocentric	Same
3D reconstruction range (degrees)	120-150 degrees	180 degrees via SmartScan (165 orbital scan + 15 shift scan)	45-50 degrees	Subject device range is within range for predicate device. Testing has demonstrated that

Characteristics & Features	Subject Device C-Beam V1.0	Predicate Device Ziehm Vision RFD 3D (K243303)	Reference Device Covidien Illumisite (K191394)	Comparison to Subject device
				reconstructed images for subject device meet clinical needs
Rotation motion source	Manual	Motorized	Manual	Same as reference device. User testing demonstrated the users can safely and effectively use manual rotation
Rotation time	18-22 seconds	48 seconds	Between 15 and 30 seconds	Subject device provides training and guidance to operators to achieve the suggested rotation time.
Number of 2D images acquired	120-450 images	Up to 400 images	-	Number of images on the subject device is calculated from range of suggested image collection parameters; reconstructed images meet clinical needs
3D resolution	512 x 512 x 485	512 x 512 x 512	-	Essentially the same as the predicate device

Characteristics & Features	Subject Device C-Beam V1.0	Predicate Device Ziehm Vision RFD 3D (K243303)	Reference Device Covidien Illumisite (K191394)	Comparison to Subject device
Workstation	Independent touchscreen workstation to manipulate 3D images	Integrated touch screen workstation to manipulate 2D/3D images	Integrated touch screen workstation	Same for relevant functionality
Angle encoding	Inertial measurement unit (IMU) attached to C-arm	Integrated rotary encoders embedded in motorized C-arm	-	IMU of subject device is comparable to rotary encoders embedded in the predicate device

***** Characteristics from host GE Elite OEC (31cm CFD) K192819

Performance Testing Summary

The design of the C-Beam 1.0 system was completed in accordance with Design Controls, 21 CFR 820 and the appropriate standards. Software and cybersecurity was documented and tested following "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions". Verification and validation testing were successfully conducted on the device.

Testing regarding electromagnetic compatibility according to IEC 60601-1-2 was performed; the system was also tested and complies with the general IEC 60601-1 standard.

Radiation dose testing included characterizing operator scatter radiation exposure, simulated patient radiation exposure, radiation scatter mapping around the C-Beam system and effectiveness of standard lead PPE in reducing exposure to the operator. All results showed an acceptable dose profile.

The image quality testing for the C-Beam system was based on a staged testing approach. Stage 1 focused on image quality characterization and robustness using expert operators, involving nominal and variations of image acquisition using phantoms. Stage 2 further explored image variability with multiple typical users operating the system to acquire images. Anthropomorphic phantom testing gathered images that covered all anatomical regions included in the device's Indications for Use. Images obtained in Stage 1 and Stage 2 were evaluated by physicians and met the criteria for clinical acceptability.

Finally, Usability and Human Factors testing was performed according to the FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices (2016). The device is found to be safe and effective to use by the intended users. .

Conclusion

The C-Beam V1.0 System is substantially equivalent to the valid predicate device and reference device based on the following criteria:

- Has the same intended use (subset of predicate)
- Has a similar Indications for Use (subset of predicate)
- Has similar technological characteristics (2D fluoroscopy images reconstructed as 3D, manual rotation like the reference device) that do not raise new questions of safety
- Uses the same operating principles for the 3D images

Electrical Safety and EMC testing, Image Quality testing, Radiation Dose characterization and formative and summative Human Factors testing further supported the substantial equivalence of the device. In summary, the C-Beam V1.0 system described in this

submission is substantially equivalent to the predicate device(s) in terms of safety and effectiveness.