July 12, 2024

CurveBeam LLC
℅ Ryan Conlon
Director of Quality and Regulatory Affairs
2800 Bronze Drive Suite #110
Suite 110
HATFIELD, PA 19440

Re: K241713
Trade/Device Name: HiRise
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: June 11, 2024
Received: June 14, 2024

Dear Ryan Conlon:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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 Radiological 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: 07/31/2026
See *PRA Statement below.*

Submission Number *(if known)*

K241713

Device Name

HiRise

Indications for Use *(Describe)*

The HiRise is intended to be used for 3-D imaging of the upper and the lower extremities and pelvis of adult and pediatric patients weighing from 40 to 450 lbs.
The device is to be operated in a professional healthcare environment by qualified health care professionals only.

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) Number: K241713

510(k) Summary

Contents

Table 5-1 Device Information

Manufacturer Name:	Curvebeam LLC
Manufacturer Address:	2800 Bronze Drive, Suite 110, Hatfield, PA
Registration Number/FEI number:	3009543051
Contact Person:	Ryan Conlon
Submission Date	July 11, 2024
Device Name:	HiRise
Classification:	Class II
Product code:	JAK
Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed Tomography X-Ray System
Device Description:	The HiRise is a Computed Tomography X-ray
Intended Use:	The HiRise is intended to be used for 3-D

Predicate Device:

Company	Device name	Product Code	510(k)	Regulation Number	Device Classification
CurveBeam, LLC	HiRise	JAK	K203187	892.1750	Class II

High-level change description:

Device Name:	HiRise
Indications for Use:	The HiRise is intended to be used for 3-D imaging of the upper and the lower extremities and pelvis of adult and pediatric patients weighing from 40 to 450 lbs. The device is to be operated in a professional healthcare environment by qualified health care professionals only.
Device class:	Class II (21 CFR 892.1750)
Product code:	JAK
510k Number/Type:	K203187 / Traditional 510k
Basic UDI-DI	8631520003CBCTDevicesCL
Date of change:	TBA
Description of Change:	Changing the maximum mA output from 6.5mA to 20mA
Reason for Change:	The HiRise is indicated for imaging of upper and lower extremities. Current imaging protocols for the HiRise have been deemed clinically acceptable, but the image

	characteristics on certain patients, based on anatomy, could be improved for enhanced contrast and lower noise. When it comes to imaging the Hip, there is naturally a significantly higher volume of adipose tissue for the X-Rays to penetrate. Therefore, a higher energy imaging protocol is proposed to enhance the image characteristics of hip scans (especially for larger patients, based on anatomy). The HiRise is a versatile device, as prior to each scan the imaging protocol is selected based on anatomy being scanned, purpose of the scan and size of patient. Due to such complexities and variabilities the HiRise is also indicated to be operated by trained professionals only.

Device Description:

Device Characteristics and Performance

The HiRise is a Cone Beam Computed Tomography Imaging Device that acquires 360-degree rotational projection sequences which are reconstructed into 3D volumetric images of the examined anatomical region. The device uses a gantry assembly, which is comprised of an X- ray source, image detector, and a motorized gantry. The gantry facilitates the acquisition of a full X-ray projection sequence by the acquisition software. For non-weight bearing scans of the lower extremity, a patient positioner accessory allows the patient to sit into a position where he/she can comfortably place his/her anatomy into the imaging bore.

The gantry assembly is mounted on vertical actuators and can travel vertically to capture weight-bearing anatomy at various heights ranging from the feet to the pelvis regions. The HiRise provides total vertical travel of 37 inches to accommodate patients of various sizes. Images produced by the HiRise can be sent electronically to a DICOM complaint image viewing software.

Key Device Components

Embedded Controller
Flat Panel Detector
Gantry Assembly
X-Ray Source
X-Ray Power Supply
Patient Platform and Positioners
Patient non-weight bearing chair
Operator Control Box
External Server

Environment of Use

The HiRise is to be used in medical facilities including hospitals, private practices, and orthopedic clinics. The HiRise should be installed and operated according to state and federal regulations regarding radiation-emitting products and the device room layout should be approved by a certified medical physicist prior to

installation.

Patient Contacting Materials

The materials that could contact the patient are listed below.

(1) Polyester patient platform lining
(2) Vinyl Transporter cushion
(3) Carbon fiber positioners
(5) Powder coated Aluminum handlebars

Changes that resulted in a new 510(k).

The proposed higher energy protocols (performance specifications) and the underlying component changes required to support the proposed protocols were evaluated. In summary, the conclusion is that this results in a performance change and there is an increased risk when it comes to patient radiation dose.

The most significant changes to the device include a redesign of the x-ray generator electronics. This includes the x-ray source (tube housing) and the x-ray power supply (high voltage power supply) along with the supporting cabling and safety electronics (isolation toroid and circuit breaker). All the above components exist in the current design but have been modified to support and enable higher energy imaging protocols to enhance the image characteristics of hip scans (especially for larger patients, based on anatomy).

The HiRise is a versatile device, as prior to each scan the imaging protocol is selected based on anatomy being scanned, purpose of the scan and size of patient. Due to such complexities and variabilities both the current and higher energy protocol versions of the HiRise are indicated to be operated by trained professionals only.

Substantial equivalence comparison table:

SUBSTANTIAL EQUIVALENCE TABLE			
Feature/ Component	**HiRise V1**	**HiRise V2**	**Variance/Rationale**
510(k) number	K203187		
Product code	JAK	No changes	
Regulation number	21 CFR 892.1750	No changes	
Indications for use	The HiRise is intended to be used for 3-D imaging of the upper and the lower extremities and pelvis of adult and pediatric patients weighing from 40 to 450 lbs. The device is to be operated in a professional healthcare environment by qualified health care professionals only.	No changes	
Principal of operation	Computed Tomography X-ray System	No changes	
Scan axis	Horizontal and vertical	No changes	
Mechanical Layout	A horizontal doughnut, with the x-ray source and flat panel detector mounted at each end of a rotating gantry. The gantry assembly lifts for scanning of the lower extremities. Rotation of the gantry to vertical imaging mode allows for the positioning and imaging of upper extremities. A non-weight bearing chair allows for non-weight bearing imaging of the foot, ankle, and knee.	No changes	
Controller	Firmware Exposure Controller	No changes	
Tube	Stationary anode, glass envelope x-ray tube. Max KV: 130kV Focal Spot: 0.5mm nominal Target Angle: 15° degrees	Rotating Anode, glass envelope x-ray tube. Max KV: 130kV Focal Spot: 0.3mm & 0.6mm nominal Target Angle: 16° degrees	The overall changes utilize a more robust tube. Change of target angle and does not impact the image sequence output quality. Both the focal spot size and target angle have been assessed in the data sets sent to board-certified radiologist and found to be of diagnostic quality.

Tube Housing	Same except for shape of aperture	Enlarged to account for the rotating anode tube	The updated Tube housing was designed with the same principles as the previous version but is designed for the updated Imaging requirements. While the tube housing has been made larger, the collimation ensures that the output is kept as low as possible and only exposes the active imaging area of the panel. All electrical changes have been verified by third party to meet IEC 60601-1 testing, including all particular and collateral standards (specifically 60601-1-2, 60601-1-3, and 60601-2-44).
High Voltage Power Supply	High frequency generator	High frequency generator updated to allow for the increased output requirements	The updated High Voltage Power supply utilizes the same design principles as the previous version but is designed for the updated Imaging requirements. All electrical changes have been verified by third party IEC 60601-1 testing, including all particular and collateral standards (specifically 60601-1-2, 60601-1-3, and 60601-2-44).
Tube voltage	100-130 kVP for CT scans	100-120 kVP for CT scans	Previous imaging protocols were limited by the system requirements. Bench testing determined optimal X-Ray tube voltage (imaging characteristics) for each anatomy and patient size. Imaging characteristics have been optimized for clinical diagnostic quality. (especially for larger patients, based on anatomy). Labeling has been updated in alignment with the new tube voltage range.
Tube current	5.5 or 6.5 mA	12 or 20 mA	Previous imaging protocols were limited by the system requirements. Bench testing determined optimal tube current (imaging characteristics) for each anatomy and patient size. Imaging characteristics have been optimized for clinical diagnostic quality.

			(especially for larger patients, based on anatomy). Labeling has been updated in alignment with the new tube current range.
Scan time	26 sec for CT	26 to 60 sec	Bench testing determined optimal imaging characteristics for each anatomy and patient size. Based on device design, maintaining an appropriate duty cycle is critical. Increases in mAs require longer scan times to maintain device duty cycle. Labeling has been updated in alignment with the new scan times.
Max exposure time	15 sec	26 sec	Bench testing determined optimal imaging characteristics for each anatomy and patient size. Higher energy (exposure time) imaging protocol is proposed to enhance the image characteristics of hip scans (especially for larger patients, based on anatomy). Labeling has been updated in alignment with the new max exposure times.
Image detector	Amorphous Silicon flat panel	No changes	
Reconstruction Algorithm	Filtered back projection with non-linear filtering for 3D Cone-Beam CT reconstruction	No changes	
Gray scale	16 bit	No changes	
3D Imaging Volume	Large FOV: 7.7” (19.5cm) height x 15.79” (40.1cm) diameter Medium FOV: 7.7” (19.5cm) height x 9.9” (25.2cm) diameter	Large FOV: 7.67” (19.5cm) height x 16.53”(42.0 cm) diameter* Medium FOV: 7.67” (19.5cm) height x 9.84” (25.0 cm) diameter* *Reconstructed Imaged Volume	Slight changes to the imaging volume are based on the new Tube housing design (see Tube housing comparison). The imaging volumes were reviewed by a board-certified radiologist and found to be of diagnostic quality. Labeling has been updated in alignment with the new Imaging volumes.
Typical resolution	LFOV: 0.3mm, MFOV: 0.25mm	Typical resolution defined by anatomy imaged	Image sequences captured utilizing all volumes, and subsequent resolutions, were included in the datasets sent to the

		0.25 mm, 0.3 mm, 0.5 mm	board-certified radiologist and found to be of diagnostic quality. Labeling has been updated in alignment with the changes in protocol resolution.
Body part scanned	Upper and lower extremities, including the Humerus, Elbow, Forearm (radius/ulna), Hand, Wrist, Hip, Femur, Knee, Shin (lower leg or tib/fib) and Ankle, and Foot.	Upper and lower extremities, including the Elbow, Hand, Wrist, Pelvis, Hip, Femur, Knee, shin (lower leg or tib/fib), Ankle, and Foot.	Minor specific protocol changes from the predicate device and are covered under the intended use (lower extremity) of both the predicate and updated HiRise. Removal of humerus, forearm (radius/ulna) particular protocols were deemed not critical as imaging of these partial anatomy protocols has not been utilized in real-world use. The specific humerus and forearm protocols configurations have been removed in the updated HiRise. Labeling has been updated in alignment with body parts imaged.
Size, inches h x d x w	57”x58”x73” (145cm x 147cm x 185cm)	No changes	
Weight, lbs	Scanner 850 lbs (385.554 kg), Transporter 250 lb (113.398 kg)	Weight changed to 900lbs	Increased weight of tube housing plus Added counterweight. Both Devices were designed to be as small as possible and to be installed in a professional medical environment with minimal modifications. Labeling has been updated in alignment with the new scanner weight.
Power Requirements	920VA	4800 VA	The power consumption has increased from the predicate in alignment with the updated imaging characteristics. All electrical changes have been verified by third party 60601-1 testing, including all particular and collateral standards (specifically 60601-1-2, 60601-1-3, and 60601-2-44). Labing has been updated in alignment with the new power requirements.
Tissue Density Range	0 to 2000 HU’s (Hounsfield Units)	No changes	
Scatter Radiation Range	0.0003 to 4.83mR	0.2 to 12.9mR	When comparing the new scatter measurement numbers to the predicate, the new numbers are higher. This can be

			expected as higher energy imaging protocols are proposed to enhance the image characteristics of hip scans (especially for larger patients, based on anatomy). The scatter radiation is in alignment with the increased imaging protocols and has not increased outside of the expected amount. Labeling has been updated in alignment with the new scatter numbers.
Patient Support Structure	Flat plastic platform and handlebars for weight-bearing imaging sequences, positioner plate for knee, transporter accessory for non-weight-bearing imaging sequences	No changes	
Detector Position	Source to Imager Distance Fixed distance from detector to x-ray beam center, parallel to axis of rotation and orthogonal to x-ray beam.	No changes	
X-Ray Beam Position	Beam size matches the 40cm x 30cm flat panel (with a narrow unexposed margin), there are two vertical beam offsets from panel center: beam offset below the panel center for foot scans, and beam offset above the panel center for other extremity scans	Beam size matches the 40cm x 30cm flat panel (with a narrow unexposed margin), there are two vertical beam offsets from panel center: Beam offset below the panel center is utilized for foot scans or any protocols that are continuous and combine with the foot. Beam offsets above the panel center for other extremity scans	The slight change in the definition of beam position was included in the datasets sent to the board-certified radiologist and found to be of diagnostic quality.
Software Capture Tool	Virtualized Windows environment based application	No changes	There is new version of the software to include the updated imaging protocols. The application is still a virtualized windows environment-based application.
Display	Computer with mouse and keyboard	No changes	
Projection Geometry	Beam collimated to a square shape, Source to Imager Distance:	Beam collimated to a square shape, Source to Imager Distance:	Slight changes to the projection geometry are based on the new Tube

	767 mm, Source to Axis of rotation Distance: 503 mm	730.55 mm, Source to Axis of rotation Distance: 466.95 mm	housing design (see Tube housing comparison). Performance testing demonstrated that new geometry does not harm image quality. The imaging volumes were reviewed by a board-certified radiologist and found to be of diagnostic quality.
Patient Positioning Guide	Foot: Circular markings on platform Knee/Hips: Accumeasure controls height of the Gantry Upper Extremity: Marks on upper extremity platform insert	No changes	
Patient Contacting Material	Powder coated Aluminum (Handlebar and Device cover), Polyester Vinyl, Carbon fibers	Powder coated Aluminum (Handlebar and Device cover), Polyester Vinyl, Carbon fibers, Nylon (fastener for hand platform & Shielding curtain) and Polycarbonate	Minor material changes, biocompatibility assessed in alignment with 10993 and do not impact the safety of the device. The instructions for use regarding contact with the machine on the predicate and new version have not changed. The User Manual on both devices recommends avoiding direct contact with the scanner using readily available materials.
Reconstruction Method	Filtered back projection with non-linear filtering for 3D Cone-Beam CT reconstruction Filtered back projection with nonlinear filtering for 3D Cone-Beam	No changes	

Design Control Activities Summary:

Device Change	Risks	Verification/Validation methods	Acceptance Criteria	Summary of Results

Change of X-Ray generating circuitry and supporting electronics
• Tube
• Tube housing.
  ○ Projection geometry
  ○ 3D imaging volume
• HVPS
• Tube current
• Increased power requirements
• Additional cooling features
• Additional bow tie filter mechanism
	Increased Dose to the patient	Internal Verification in alignment with all internal testing of previous HiRise.
		
		External third-party testing by ASCA testing facility to 60601-1 and all applicable collateral and particular standards.
		
		*Note: Bowtie filter not used in this update. Future use will be enabled under the same design controls employed by the current QMS.
			Passes all internal verification with no anomalies causing increased risk.
			
			Passing all third party testing to all applicable requirements.
				All applicable test plans passed with no anomalies increasing risk.
				
				Completed 3rd party testing with no outstanding failures.

Increased energy output protocols • Scan time • Max Exposure time • Increased mA capabilities		Validation by fellowship-trained MSK radiologist.	Updated labeling A letter stating Images of new imaging protocols are clinically acceptable and adequate diagnostic quality.	Labeling updated. Letter from fellowship-trained MSK radiologist validating images to be clinically acceptable and of clinical adequate diagnostic quality.
Increased weight of the system	Negligible increase (approx. 50 pounds)	No verification required	Updated labeling	Labeling updated.

Substantial Equivalence Discussion:

The overall technology, key components and intended use of the HiRise Computed Tomography x-ray system and the predicate device are substantially similar, with certain inconsequential differences as described.

Both the predicate HiRise and updated HiRise devices image extremities of similar bone density ranges and utilize a similar gantry to capture the desired anatomy. Images of the difference between the two devices have been reviewed by a radiologist and have been found to be of adequate diagnostic quality.

The combination of performance testing internally, safety and functional testing by a certified third-party testing body, and clinical review of images by a radiologist indicate that HiRise is safe and effective when used as labeled.

Safety and Effectiveness Information:

The HiRise Computed Tomography X-ray system is a Class II medical device.

The HiRise Computed Tomography X-ray system complies with applicable FDA and international standards pertaining to electrical, mechanical, software, EMC, and radiation safety of medical devices.

Conformity

The HiRise device has been tested to the following standards to ensure safety, effectiveness, and compliance with industry norms:

IEC 60601-1:2005, Edition 3.2, 08/2020
IEC 60601-1-3:2008, Edition 2.2, 01/2021
IEC 60601-1-6, Edition 3.2, 07/2022
IEC 60601-2-44, Edition 3.2, 03/2016 (12-302)
IEC 62366-1, Edition 1.1, 06/2020
IEC 60825-1, Edition 3, 05/2014
IEC 62304:2006 Ed.1 +A1, 06/2015
IEC 60601-1-2, Edition 4, 02/2014
IEC 61223-3-5, Edition 2.0, 09/2019 (12-328)
NEMA PS 3.1-3.20, 2023e (12-352)
NEMA PS 3.1-3.20, 2023d (12-349)
61223-2-6 Second Edition 2006-11 (12-266)

FDA Guidance

The following FDA Guidance Documents were referenced to the extent they were applicable in the preparation of this 510(k) Submission

- Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices
- Guidance for the Content of Premarket Submissions for Device Software Functions
- Applying Human Factors and Usability Engineering to Medical Devices
- Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
- Pediatric Information for X-ray Imaging Device Premarket Notifications

Conclusion:

CurveBeam, LLC has demonstrated through its comparison of characteristics with the predicate device and comparison of performance data with the predicate device that the HiRise Computed Tomography X-ray System is substantially equivalent to the predicate device.