CurveBeam, LLC
% Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
WARREN NJ 07059

November 18, 2020

Re: K203187
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: October 25, 2020
Received: October 27, 2020

Dear Mr. Yungvirt:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-

combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203187

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.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5
510(k) Summary

K203187

Contents

Table 5-1 Device Information

510 (k) Submitter/Owner	CurveBeam, LLC 2800 Bronze Drive, Suite 112 Hatfield, PA 19440 Phone: 267-483-8081 Fax: 267-483-8086
Contact Person	Ryan Conlon Director of Quality and Regulatory Affairs 267-483-8081 Email: Ryan.Conlon@curvebeam.com
Date Prepared	August 14, 2020
Trade Name	HiRise
Common Name	Computed tomography x-ray system
Classification Name	Computed tomography x-ray system

Product Code	JAK
510(k) Type	Traditional
Regulation Number	892.1750
Device Classification	Class II

This is the first 510(k) submission for this device. There were no prior submissions.

Predicate Device:

Table 5-2 Predicate Device

Company	Device name	Product Code	510(k)	Regulation Number	Device Classification
CurveBeam, LLC	HiRise	JAK	K180727	892.1750	Class II

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 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
(4) Powder coated Aluminum handlebars

Table 5-3 LineUP Substantial Equivalence Technical Characteristics

	CurveBeam HiRise Computed tomography x-ray system	**CurveBeam LineUP Computed tomography x-ray system**	**Variance Explanation**
510(k) number		K180727	
Product code	JAK	JAK	
Regulation number	21 CFR 892.1750	21 CFR 892.1750	
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.	The LineUP is intended to be used for 3-D imaging of the foot, knee, hand, and elbow regions to visualize and assess the osseous and certain soft tissue structures, including joint spaces, bone angles and fractures. It is also intended to capture 2-D images (standard plain x-ray projections) of the foot, knee, hand, and elbow regions. This modality is anticipated to be applicable to pediatric* cases as well as adults, when appropriate diagnosis of a given condition is considered necessary. Patient parameters: 50 lbs to 400 lbs *2D Imaging not intended for pediatric use	Datasets of the humerus, elbow, forearm, hand, wrist, pelvis/hips, femur, knee, shin (lower leg or tib/fib) and foot/ankle were reviewed by a board-certified radiologist and found to be of diagnostic quality. The increased weight range has been tested and verified by third party 60601-1 testing.

Principle of Operation	Cone Beam Computed Tomography X-Ray	Cone Beam Computed Tomography X-Ray & 2D Imaging	
Scan axis	Horizontal and vertical	Horizontal and vertical	Image sequences captured utilizing the gantry in vertical scanning mode were included in the datasets sent to the board-certified radiologist and found to be of diagnostic quality.
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.	A horizontal doughnut, with the x-ray source and flat panel detector mounted at each end of a rotating gantry. Gantry assembly lifts for scanning of the knee. Reclining Transporter allows for positioning of upper extremity in bore.	The addition of anatomy above the knee use the same CBCT concept as foot, ankle, and knee.
Controller	Firmware Exposure Controller	Firmware Exposure Controller	
Tube	Stationary anode, glass envelope x-ray tube. Max KV: 130kV Focal Spot: 0.5mm nominal Target Angle: 15 degree	Stationary anode, glass envelope x-ray tube. Max KV: 130kV Focal Spot: 0.5mm nominal Target Angle: 20 degree	Change of target angle does not impact the image sequence output quality. HiRise utilizes a more robust tube with a smaller target angle.
Tube Housing	Same except for shape of aperture	Same except for shape of aperture	New aperture allows for appropriate output
High Voltage Power Supply	High frequency generator	High frequency generator	No change, same supply
Tube voltage	100-130 kVP for CT scans	100-120 kVP for CT scans 60 kVp for 2D X-Rays	Bench testing determined optimal X-Ray tube voltage for each anatomy and patient size Higher kVP was determined to be required to clinically image the new anatomy (hips and pelvis). 2D X-Rays are not required for use of the HiRise
Tube current	5.5 or 6.5 mA	5 mA	Increased tube current was required to provide diagnostic quality image sequences in the new anatomy (hips and pelvis).
Scan time	26 sec for CT	21 sec for CT	CT: HiRise is slightly slower to allow for greater exposure time required for the denser anatomy. Image quality performance was verified with Bench Testing.

Max exposure time	8.7 sec	9 sec	Similar exposure times
Image detector	Amorphous Silicon flat panel	CMOS flat panel	Detector performance testing verified image quality met requirements
Reconstruction Algorithm	Filtered back projection with non-linear filtering for 3D Cone-Beam CT reconstruction	Filtered back projection with non-linear filtering for 3D Cone-Beam CT reconstruction	Both the HiRise and the LineUP use the same reconstruction engine.
Gray scale	16 bit	14 bit	The panel uses a 16 bit panel to utilize a larger dynamic range of the imaging sequences.
3D Imaging Volume	Large FOV: 8" (20cm) height x 16" (40cm) diameter Medium FOV: 8" (20cm) height x 10" (25cm) diameter	20cm (high) x 35 cm (diameter)	Image sequences captured utilizing both volumes were included in the datasets sent to the board-certified radiologist and found to be of diagnostic quality.
Typical resolution	LFOV: 0.3mm, MFOV: 0.25mm	0.3 mm voxel	Image sequences captured utilizing both volumes, and subsequent resolutions, were included in the datasets sent to the board-certified radiologist and found to be of diagnostic quality.
Body part scanned	Humerus, elbow, forearm (radius/ulna), hand, wrist, pelvis/hips, femur, knee, shin (lower leg or tib/fib) and ankle/foot.	Foot, knee, hand, elbow	Datasets of the humerus, elbow, forearm (radius/ulna), hand, wrist, pelvis/hips, femur, knee, shin (lower leg or tib/fib) and foot/ankle are included in Section 37
Size, inches h x d x w	57"x58"x73" (145cm x 147cm x 185cm)	62.63"x49.01"x51.71"	Both devices designed to be easily installed and to fit in a professional healthcare environment with minimal modifications.
Weight, lbs	Scanner 850 lbs (385.554 kg), Transporter 250 lb (113.398 kg)	Scanner 750 lbs (340.194 kg), Transporter 250 lb (113.398 kg)	HiRise is larger and has more components to accommodate additional anatomy.
Power Requirements	920VA	1150VA	HiRise is rated a slightly lower power consumption.
Tissue Density Range	0 to 2000 HU's (Hounsfield Units)	0 to 2000 HU's (Hounsfield Units)	
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	Flat plastic platform and handlebars for weight-bearing foot/ankle, positioner plate for knee, transporter accessory for upper extremities and non-weight-bearing foot	New support structures permit scanning of additional anatomical regions. Support structures tested to Standards specified in Section 9 – Declarations of Conformity and Summary Report
Detector Position	Source to Imager Distance Fixed distance from detector to x-ray beam center, parallel to	Source to Imager Distance Fixed distance from detector to x-ray beam center, parallel to axis of	

	axis of rotation and orthogonal to x-ray beam.	rotation and orthogonal to x-ray beam.	
X-Ray Beam Position	Beam size matches the 40cm x 31cm 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 30cm x 30cm flat panel detector (with a narrow unexposed margin), the beam center is vertically positioned below the panel center (towards the bottom of the FOV) where the densest bones in the foot are located.	HiRise and LineUP utilize similar two offsets to image different parts of the anatomy described in the intended use.
Software Capture Tool	Virtualized Windows environment based application	Virtualized Windows environment based application	
Display	Computer with mouse and keyboard	Computer with mouse and keyboard	
Projection Geometry	Beam collimated to a square shape, Source to Imager Distance: 767 mm, Source to Axis of rotation Distance: 503 mm	Beam collimated to a square shape, Source to Imager Distance: 767 mm, Source to Axis of rotation Distance: 528 mm	Slightly different geometry accommodates patients up to the Hip. Performance testing demonstrated that new geometry does not harm image quality.
Patient positioning guide	Foot: Circular Markings on Platform	Foot: Circular Markings on Platform	HiRise includes a tool to measure the height of the knee and hips. The
	Knees/Hips: Accumeasure controls height of Gantry	Knees: Markings on Knee Positioner	
	Upper Extremity: Marks on upper extremity platform insert	Upper Extremity: Marks on upper extremity platform insert	
Patient Contacting Materials	(1) Polyester patient platform lining (2) Vinyl Transporter cushion (3) carbon fiber positioners (4) Powder coated Aluminum handlebars	(1) Polyester patient platform lining (2) Vinyl Transporter cushion (3) carbon fiber positioners (4) Lexan panel shield (5) Powder coated Aluminum handlebars	The instructions for use regarding contact with the machine on the LineUP and HiRise are similar. The User Manual on both devices recommends avoiding direct contact with the scanner using readily available materials.

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 described henceforth.

Both the HiRise and LineUP devices image extremities of similar bone density ranges and utilize a similar gantry to capture the desired anatomy. They are both able to scan feet and knees in a bilateral position as well as scan the hand and elbow regions. The HiRise has an added capability to scan the entire lower up to the pelvis and to scan the entire upper extremities. The additional support structures on the HiRise have been tested to applicable safety standards. Images of the additional anatomy have been reviewed by a radiologist and have been found to be of adequate diagnostic quality.

To establish equivalency in performance, image quality phantoms were scanned in the HiRise and evaluated by a medical physicist. Also, the scans were reviewed by a radiologist and found to be of

diagnostic quality.

The HiRise uses a similar X-Ray tubehead and the same power supply as the LineUP. The LineUP utilizes a CMOS flat panel image detector while the HiRise uses an amorphous silicon flat panel detector to capture projection images. Performance testing demonstrated that the image quality of the amorphous silicon flat panel is statistically equivalent to that of the predicate.

The combination of performance testing by a medical physicist, 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:

AAMI ES60601-1:2005+C1; A1
IEC 60601-1:2005, 3rd Edition+C1; C2; A1
IEC 60601-1-3, Edition 2.1, 04/2013
IEC 60601-1-6, Edition 3.1, 10/2013
IEC 62366, Edition 1.1, 01/2014
IEC 62304:2006 Ed.1 +A1, 06/2015
IEC 60601-2-44, Edition 3.2, 03/2016
IEC 60601-1-2, Edition 4, 02/2014
IEC 61223-3-5, first edition, 08/2004
NEMA PS 3.1-3.20, 2016
IEC 60825-1, Edition 3, 05/2014

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 Submission Of Premarket Notifications for Medical Image Management Devices

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Applying Human Factors and Usability Engineering to Medical Devices
- Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- 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
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions

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.