Dear Dave 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

[Signature]

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K170789

Device Name
In Reach

Indications for Use (Describe)
The In Reach is intended to be used for 3-D imaging of the hand, wrist, elbow, knee, foot, and ankle regions, to visualize and assess the osseous and certain soft tissue structures, including joint spaces, bone angles and fractures. This modality is anticipated to be applicable to pediatric* cases as well as adults*, when appropriate diagnosis of a given hand, wrist, elbow, knee, foot or ankle condition is considered necessary.

* Patient parameters: 50 lbs to 400 lbs

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.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASff@fda.hhs.gov

"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 3
510(k) Summary

| 510 (k) Submitter/Owner | CurveBeam, LLC  
175 Titus Ave, Suite 300  
Warrington, PA 18976  
Phone: 267-483-8081  
Fax: 267-483-8086 |
|-------------------------|--------------------------------|
| Contact Person          | Senior Project Engineer  
267-483-8081  
Email: Stuti.singh@curvebeam.com |
| Date Prepared           | April 25, 2017 |
| Trade Name              | In Reach |
| 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 |

Predicate Device:

<table>
<thead>
<tr>
<th>Company</th>
<th>Device name</th>
<th>Product Code</th>
<th>510(k)</th>
<th>Regulation Number</th>
<th>Device Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>CurveBeam, LLC</td>
<td>PedCat</td>
<td>JAK</td>
<td>K113548</td>
<td>892.1750</td>
<td>Class II</td>
</tr>
</tbody>
</table>

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

The In Reach is intended to be used for 3-D imaging of the hand, wrist, elbow, knee, foot, and ankle regions, to visualize and assess the osseous and certain soft tissue structures, including joint spaces, bone angles and fractures. This modality is anticipated to be applicable to pediatric* cases as well as adults*, when appropriate diagnosis of a given hand, wrist, elbow, knee, foot or ankle condition is considered necessary.

* Patient parameters: 50 lbs to 400 lbs

Device Description:

The In Reach is a dedicated X-Ray imaging device that acquires a 360 degree rotational X-ray projection sequence and reconstructs a three-dimensional volume of the examined anatomical region, comprised of a stack of slices of specified thickness. The device uses a gantry assembly, which is comprised of an X-ray source, image detector, and motorized gantry. The gantry facilitates the acquisition of a full X-ray projection sequence by the acquisition software.

The gantry assembly is mounted on vertical rails and can travel up and down those rails depending on the anatomical region of interest and patient scanning position. The vertical travel allows placement of the field-of-view opening (bore) at the desired height depending on the extremity to be scanned. The In Reach provides total vertical travel of 23.5 inches to facilitate placement of the leg or arm extremity into the bore, one limb at a time. The In Reach provides software tools to measure distances and angles on slices and 3D renderings. Images produced by the In Reach can be printed or exported on optical media, or sent electronically. The In Reach software also displays the selected set of reconstructed slices and 3D renderings on the workstation monitor for viewing.

Substantial Equivalence Summary:

The overall technology, key components and intended use of the In Reach Computed Tomography x-ray system and the predicate device (CurveBeam PedCat) are substantially similar, with certain inconsequential differences described henceforth. The In Reach Computed Tomography X-ray system is designed and manufactured by CurveBeam and uses the same X-ray tubehead and substantially similar X-ray power supply and Varian flat panel detector technology as the PedCat. The only difference is the detector size (Varian 2520 in the In Reach vs. Varian 3030 in the PedCat), but the underlying technology is near-identical, including internal circuits and interface. The In Reach uses the same software components as the predicate device (PedCat), with minor variations to accommodate scanning of additional extremities. In Reach has the same technological characteristics as the predicate device in terms of the employed Cone Beam CT technology for 3-D imaging of anatomical features of similar bone structures and tissue density ranges. Although the intended use differs in the target anatomies, the
intended diagnostic data (osseous tissue details) and applicable tissue densities are very similar. The In Reach also differs in its mechanical layout and the patient support structure, since it is intended for 3-D imaging of hand, wrist, forearm, elbow; and knee, ankle & foot in a non-weight bearing position.

In the In Reach the patient support structure is a rigid platform, inside a scan opening (bore) where the patient places one hand, wrist, forearm or elbow. For non-weight bearing scanning of the knee, ankle or foot, the applicable lower extremity is placed directly in the scan opening (bore). In the predicate device, the patient stands in a weight bearing position on a rigid platform, or utilizes the included seat cushion to enable scanning in a seated position, while the targeted anatomy (foot & ankle region) is scanned.

The rotating gantry in the In Reach, on which the x-ray source and the detector panel are mounted, is enclosed in a low-density plastic cover with a stainless steel shielding attached to it, while the scan opening (bore) is exposed in the center, similar to a doughnut hole, where the patient’s extremity is placed. The predicate device has a rotating gantry, on which the x-ray source and the detector panel are mounted, enclosed in a low-density plastic cover, permitting the patient’s feet to be placed in its own “doughnut-hole” opening. The In Reach gantry rotates around a horizontal axis, while the predicate device gantry rotates around a vertical axis.

The above mechanical differences have no impact on how the projection data is captured and reconstructed, as compared to any Cone Beam CT (CBCT) device, including the predicate device. To establish this, test scans were performed on a resolution and density phantom, water equivalent material phantom, and anatomic hand, foot and knee phantoms (hand/foot/knee skeleton enclosed in soft tissue equivalent material). The characteristics of the resultant volume of the resolution and density phantom and the water equivalent phantom were authentic and accurate representations of the imaged objects, within the expected tolerance for a CBCT device, and very similar to the predicate device. The specific parameters evaluated included spatial resolution (visible line pairs), uniformity of Hounsfield Units (HU’s) in water equivalent material, and HU values of various density materials in the resolution and density phantom. The hand, elbow, foot and knee phantom scans showed osseous details and joint spaces very similar to the predicate device and were evaluated and approved by a board-certified radiologist.

The position of the rectangular x-ray beam with respect to the target anatomy is very similar to the predicate device. In both cases, the beam is centered slightly offset from the center of the Field of View.

The scatter radiation (in the surrounding space) was measured in a comprehensive manner as well, and the values were found to be in a very low range and comparable to the predicate device.

In the software domain, although there are expected user interface differences with the predicate device, as well as differences in certain implementation details, the frame capture tools are identical (provided by Varian, the supplier of the flat panel detector) and both use FDK back-projection algorithm for CBCT reconstruction.

The above tests and analysis establishes that despite certain implementation differences, the In Reach is substantially equivalent to the predicate device.
Safety and Effectiveness Information:

The In Reach Computed tomography x-ray system is a Class II medical device.

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

- IEC 60601-1, 3rd Edition + C1; C2, 12/2005
- IEC 60601-1-2, fourth edition, 2014
- IEC 60601-1-3, second edition + A1 01/2008
- IEC 60601-1-4, 1.1 edition, 04/2000
- IEC 60601-1-6, third edition, 01/2010
- IEC 61223-3-5, first edition, 08/2004
- NEMA PS 3.1-3.20

FDA Guidance

The following FDA Guidance Documents were regarded 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
Conclusion:

CurveBeam, LLC has demonstrated through its comparison of characteristics with the predicate device and comparison of performance testing with the predicate device that the In Reach Computed tomography x-ray system is substantially equivalent to the predicate device.