July 13, 2023

Canon Medical Informatics, Inc.
℅ Dr. Jay Vaishnav
Principal Regulatory Affairs Strategist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343

Re: K223261
Trade/Device Name: Open Rib
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: June 6, 2023
Received: June 6, 2023

Dear Dr. Jay Vaishnav:

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,

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
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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.

Submission Number *(if known)*

K223261

Device Name

Open Rib

Indications for Use *(Describe)*

Open Rib is image analysis software for chest CT images. Open Rib offers a visualization of the unfolded rib cage that allows a physician to instantly view the full rib anatomy and should be used as an additional view in adjunct to conventional multiplanar reformat views. Open Rib offers geometric and HU measurement tools.

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) #: K223261

510(k) Summary

Prepared on: 2023-07-07

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Open Rib
Common Name	Computed tomography x-ray system
Classification Name	System, X-Ray, Tomography, Computed
Regulation Number	892.1750
Product Code	JAK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K123584	SYNGO, CT BONE READING	JAK

Device Description Summary

21 CFR 807.92(a)(4)

Open Rib is image analysis software for chest CT images. The software resides on the Vitrea Advanced Visualization (AV) platform.

Open Rib offers a visualization of the unfolded rib cage called an “unfolded cylindrical projection” (UCP) that allows a physician to instantly view the full rib anatomy and should be used as an additional view in adjunct to conventual multiplanar reformat views. Open Rib offers geometric and HU measurement tools.

The images can be directly exported to PACS and batch saved.

HOW THE DEVICE FUNCTIONS

The device is a software device that operates on chest CT images in order to generate an unfolded cylindrical projection view of the rib cage. The user has the ability to edit the segmentation of the ribs.

SCIENTIFIC CONCEPTS THAT FORM THE BASIS OF THE DEVICE

The main algorithms used to generate the UCP view involve rib cage segmentation based on standard (non-AI based) segmentation methods, and rib cage unfolding performed by mathematical projection of the rib cage from Cartesian coordinates into unfolded cylindrical coordinates.

PHYSICAL AND PERFORMANCE CHARACTERISTICS OF THE DEVICE

The device is a software algorithm that operates on thoracic CT images. Device performance was validated on thirty cases, in a qualitative study by three US board-certified radiologists. In addition to this testing, software verification and validation activities were completed to ensure that the Open Rib software functions remained consistent with the software requirements. The software achieved all product release criteria.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Open Rib is image analysis software for chest CT images. Open Rib offers a visualization of the unfolded rib cage that allows a physician to instantly view the full rib anatomy and should be used as an additional view in adjunct to conventional multiplanar reformat views. Open Rib offers geometric and HU measurement tools.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The device has different indications for use in comparison to the predicate device. The differences follow:

• Both the subject and predicate devices offer a visualization of the rib cage. The subject device is indicated only for visualization of the ribs, whereas the predicate device is indicated for visualization of the rib and spine. Limiting the device indications to ribs only does not constitute a new intended use.

• The subject device uses an unfolded cylindrical projection instead of curved MPR to generate unfolded rib views. The indications have been modified to reflect the difference. As the device output remains the same, the use of a different method to obtain it does not affect the device's intended use.

• While the subject device offers similar measurement and visualization capabilities, the IFU is being modified for clarity and brevity. This change does not create a new intended use.

• Any indications related to pathologies or improvements in user workflow have been removed. Reducing the scope of the indications does not create a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The device has different technological characteristics from the predicate device. The following is a summary comparison:

• Both devices operate on chest CT images and output unfolded views of the ribs. However, the algorithms used to generate the unfolded rib views are different. The subject device uses an unfolded cylindrical projection instead of curved MPR to generate unfolded rib views.

• Both devices offer similar visualization tools. All views that the subject device offers are offered by the predicate device. The predicate device offers one additional visualization tool, inverted MIP view, that is not present in the subject device. Inverted MIP view is not necessary for visualization of the rib cage.

• The subject device offer distance line, marker and arrow geometric tools and a pixel lens HU tool. The predicate offers polyline and angle geometric tools and ROI circle, ROI polygonal, ROI freehand, & VOI sphere HU tools but the subject device does not.

• Both devices offer manual editing capability for the unfolded rib view.

• The predicate device offers inverted MIP view and automated rib labeling. The subject device does not.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Open Rib was tested on 30 chest CT cases with volume ≤ 1mm and reconstructed with a bone kernel. The 30 cases all met the following inclusion criteria:

- CT chest images with most of the ribs
- Slice thickness ≤ 1mm
- Bone reconstruction kernel

with the following excluded:

- Significant motion artifacts from patient breathing present on image
- Severe kyphosis
- Reconstruction kernel other than bone used

The datasets included were representative of most routine chest CT protocols and applied to a variety of clinical indications, including routine diagnostic chest, oncologic chest studies and emergency/trauma studies.

The 30 cases included 12 normal cases (40%) and 18 abnormal cases such as rib fracture(s), bony lesions, both of rib fracture(s) and bony lesions and kyphosis (60%). 20 cases were non-contrast images (66.7%) and 10 cases were contrast images (33.3%). 30 cases acquired with various CTs were used. (Canon:17, Siemens:8, GE:4, Philips:1).

The evaluators were U.S. board-certified radiologists. Each evaluator reviewed 10 cases. The cases were evenly distributed between evaluators.

The evaluators were subsequently presented a list of questions asking about the clinical utility and effectiveness of the unfolded rib view, the measurement tools, and the overall application and workflow. A “pass” result required positive answers to all questions.

All three radiologist readers completed the questionnaire and responded "yes" to each of the questions. The device thus met pass criteria for visualization of the rib cage. The results demonstrate that the device successfully generates unfolded cylindrical projections of the ribs that are an adjunct to a conventional MPR view.

In addition to this testing, software verification and validation activities were completed to ensure that the Open Rib software functions remained consistent with the software requirements. The software achieved all product release criteria.