CRUXELL Corporation
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200
IRVINE CA 92620

July 29, 2021

Re: K211317
Trade/Device Name: CRUXVIEW
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: April 22, 2021
Received: April 30, 2021

Dear Priscilla Chung:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211317

Device Name
CRUXVIEW

Indications for Use *(Describe)*
The CRUXVIEW is a software intended for using and managing dental x-ray image sent by Cruxcan image plate scanner, storing the images and allowing the user to process and examine the images in order to achieve improved diagnoses.

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

(K211317)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 26, 2021

1. **510K Applicant / Submitter:**
   CRUXELL Corp.
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   Tel : +82-42-935-2554
   Fax : +82-42-931-2554

2. **Submission Contact Person**
   LK Consulting Group USA, Inc.
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   Priscilla Juhee Chung
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3. **Device**

- Trade/Device Name: CRUXVIEW
- Regulation Number: 21 CFR 872.1800
- Regulation Name: Extraoral Source X-Ray System
- Regulatory Class: Class II
- Product Code: MUH

4. **Predicate Device**

- Manufacturer: Orion Corporation Soredex
- Trade/Device name: Digora for Windows 2.0 (K983267)
- Regulation number 21 CFR 872.1800
- Regulation name: Extraoral Source X-Ray System
- Regulatory Class: Class II
- Classification Product Code: MUH

5. **Description:**

The CRUXVIEW is dental x-ray image management software which provides various

features to acquire, transfer, edit, display, and store scanned dental images which is specifically for a 510k cleared device (K183637), Cruxcan (CRX-1000). It also provides server/client model which allow users to upload and download the images and patient information from any workstations in the network environment.

CRUXVIEW consists of two parts: CRUXVIEW Viewer and CRUXVIEW Server. CRX-1000 sends the scanned image to the CRUXVIEW viewer. The CRUXVIEW viewer sends the received image to the CRUXVIEW Server. The CRUXVIEW Viewer searches the image stored in the CRUXVIEW Server and shows the image to the user. The subject device has various functions for users' needs including length and angle measurement functions. The CRUXVIEW supports DICOM file formats.

8. Indications for Use

The CRUXVIEW is a software intended for using and managing dental x-ray image sent by Cruxcan image plate scanner, storing the images and allowing the user to process and examine the images in order to achieve improved diagnoses.

9. Substantial Equivalence Discussion:

Comparison Chart

	Subject Device	Predicate Device
Device Name	CRUXVIEW	DIGORA FOR WINDOWS 2.0
510k #	K211317	K983267
Manufacturer	CRUXELL Corp.	ORION CORPORATION SOREDEX
Indications for Use	The CRUXVIEW is a software intended to using and managing dental x-ray image sent by Cruxcan image plate scanner, storing the images and allowing the user to process and examine the images in order to achieve improved diagnoses.	The digora for windows is a software intended to using and managing dental x-ray image sent by digora image plate scanner, storing the images and allowing the user to process and examine the images in order to achieve improved diagnoses. The software can also support other imaging devices such as larger size imaging plate scanners and intraoral video cameras.
Network Protocol	TCP/IP	TCP/IP
Operating System	Windows 10	Windows XP or higher
Monitor (minimum required)	1280x1024 SXGA	1024x768 True color XGA
RAM	4GB or more	1GB or more
Storage	100GB or more	100GB or more
Output Data	DICOM, BMP, JPEG, TIFF	DICOM, BMP, JPEG, TIFF
Backup	Yes	Yes
Dynamic range	16bit	16bit
DICOM compatibility	DICOM 3.0 compliant	DICOM 3.0 compliant

Image function	Pan, Rotate, Flip, Contrast/Histogram, Invert, Zoom In/Out, Reset	Rotate, Flip, Contrast/Histogram, Invert, Zoom In/Out, Reset, Color controller
Overlay function	Text, line, rectangle, circle	Text, line
Measurement	Distance, angle	Distance, angle

12. Substantial Equivalence Discussion

CRUXVIEW is substantially equivalent to DIGORA FOR WINDOWS 2.0 (k983267) made by ORION CORPORATION SOREDEX in indications for use, technological characteristics including network protocol, operating system, and data format.

The difference between the two devices is whether to support color change of the original image. Even if the subject device does not support this feature, since this is an additional function just to suit the color preference of the user, this does not raise a question in substantial equivalence.

Based on the information we provided here in and the results of the performance test including SW validation, we concluded that the subject device is substantial equivalent to the predicate device.

13. Performance Tests

- SW Validation for Viewer & Server
- Performance test for accuracy of measurement function

The test results of the tests performed on the subject device supported that it is substantially equivalent to the predicate device.

The CRUXVIEW conforms with the following FDA-recognized standards.

- ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements
- ISO 14971 Medical devices - Application of risk management to medical devices
- IEC 62304 Medical device software - Software life cycle processes
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices

The followings are the FDA guidance documents utilized in the development of the subject device.

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

14. Conclusions:

Based on the information provided in this premarket notification, CRUXELL Corp. concludes that the CRUXVIEW is substantially equivalent to the predicate device as described herein in.