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

February 12, 2019

Re: K183637
Trade/Device Name: CRUXCAN (CRX-1000)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: December 10, 2018
Received: December 26, 2018

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K183637

Device Name

CRUXCAN (CRX-1000)

Indications for Use *(Describe)*

The CRUXCAN (CRX-1000) is indicated for capturing, digitization and processing of intra-oral x-ray images stored in imaging plate recording media.

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

(K183637)

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

Date: Feb 5, 2019

1. 510K Applicant / Submitter:

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2. Submission Contact Person

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3. Device

- Proprietary Name: CRUXCAN (CRX-1000)
- Common Name: Dental PSP Scanner
- Classification: Class II (21 CFR 872.1800)
- Product Code: MUH
- Regulation Name: Extraoral source x-ray system

4. Predicate Devices

4.1. Digora Optime (K041050) by Soredex Instrumentariumn Corporation

- Common Name: Dental PSP Scanner
- Classification: Class II (21 CFR 872.1800)
- Product Code: MUH
- Regulation Name: Extraoral source x-ray system

4.2. Digora Optime (K133231) by Instrunmentariuin Dental

- Common Name: Dental PSP Scanner
- Classification: Class II (21 CFR 872.1800)
- Product Code: MUH
- Regulation Name: Extraoral source x-ray system

5. Device Description:

The CRUXCAN (CRX-1000) is a dental computed radiography system and is intended to produce digital X-Ray images for dental radiography purposes. It consists of a scanner, reusable imaging plates and workstation software. This device scans X-Ray exposed imaging plate and produces X-Ray image in digital form. Then, digital image is transferred to workstation for further processing and routing.
The design features a built-in erase function and a color touch-screen LCD panel without physical push buttons for device operation. This device is intended to be operated in a radiological environment by qualified staff.
The Imaging Plate is a polyester film made of densely applied particles of inorganic crystals called photostimulable phosphor. It is a flexible X-ray sensor for the CR system which can be used with a conventional medical X-ray imaging system and can be employed as a substitute for the screen/film system. The phosphor layer has a function of recording an X-ray image. This photostimulable phosphor is a special luminescent material which stores X-ray energy and emits light proportional to the stored X-ray energy when stimulation energy such as visible light is irradiated onto it.
CRUXCAN TWAIN Driver and Viewer which transmit and display images are substantially equivalent to the predicate device software as well in terms of functions and principle of operations. The User interface is slightly different but the differences in design do not raise questions in device effectiveness.

8. Indications for Use

The CRUXCAN (CRX-1000) is indicated for capturing, digitization and processing of intra-oral x-ray images stored in imaging plate recording media.

9. Substantial Equivalence Discussion:

	Subject Device	Predicate Device	Reference Device	SE Note
510k #	K183637	K041050	K133231	
Device Name	CRUXCAN	Digora Optime	Digora Optime	
Manufacturer	CRUXELL Co., Ltd.	Soredex Instrumentariumn Corporation	Instrunmentariuin Dental	-
Indications for Use	The CRUXCAN (CRX-1000) is indicated for capturing, digitization and processing of intra-oral x-ray images stored in imaging plate recording media.	The Digora Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.	The DIGORA0 Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.	Equivalent
Communication	TIFF / Raw Format	DICOM	DICOM	No issue on safety and effectiveness
Power Supply	50 – 60 Hz 100 – 240 V ~	50 – 60 Hz 100 – 240 V ~	50 – 60 Hz 100 – 240 V ~	Equivalent
Operating System	Windows 10 or higher	Windows NT 4.0/2000/XP	Windows 7 or 8	Equivalent
X-ray Absorber	Imaging Plate	Imaging Plate	Imaging Plate	Equivalent
Cassette Size	Size 0 : 22 x 31mm Size 1 : 24 x 40mm Size 2 : 31 x 41mm Size 3 : 27 x 54mm	Size 0 : 22 x 31mm Size 1 : 24 x 40mm Size 2 : 31 x 41mm Size 3 : 27 x 54mm	Size 0 : 22 x 31mm Size 1 : 24 x 40mm Size 2 : 31 x 41mm Size 3 : 27 x 54mm	No issue on safety and effectiveness
Pixel Size	25 um 50 um	40 um 64 um	30um 60um	No issue on safety and effectiveness
Dynamic Range (Acquisition)	8bit /16 bit	14 bit	14 bit	Equivalent
Resolution	14.0lp/mm @ 25um	12.5 lp/mm @ 40um	16.7 lp/mm@30um	No issue on safety and effectiveness
Imaging Plate Performance - DQE - MTF - Max. Resolution	DQE at 10% efficiency : 2.8 lp/mm MTF at 3lp/mm : 35% Max resolution : 25um	DQE at 10% eff : 2.4 lp/mm MTF at 3lp/mm : 32% Max resolution : 40um	DQE at 10% eff : 2.4 lp/mm MTF at 3lp/mm : 32% Max resolution : 30um	No issue on safety and effectiveness

The CRUXCAN is substantially equivalent to the predicate device, Digora Optime (K041050) and Digora Optime (K133231) in indications for use, imaging principle, and physical characteristics. The CRUXCAN also has similarities in power supply, operating system, X-ray absorber and imaging plate size.

The differences of the three devices are pixel size, dynamic range, resolution, and image plate performance. As compared in the chart above, the subject device has better or substantially equivalent resolution, DQE, and MTF data. The smaller pixel size of subject device than

the predicate device offers wider dynamic range with storing image data using more bits.

The imaging plates are similar to the predicate plates and they employ the same technology and principle of operation. Despite the minor differences, the results of the performance testing provided in the submission support that the subject device is substantially equivalent to the predicate device.

10. Performance Tests

- Performance studies were conducted on the device imaging plate according to the FDA guidance "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices".
- The CRUXCAN (CRX-1000) has been tested for Electromagnetic Compatibility and Safety in accordance with the IEC60601 standards. The devices operated within the EMI emission, susceptibility and static discharge levels specified in the IEC 60601 standards.
- Software Validation Test

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

Clinical testing was not necessary for the subject device, in order to demonstrate substantial equivalence.

11. Conclusions:

Based on the information provided in this premarket notification, CRUXELL Corp. concludes that the CRUXCAN (CRX-1000) is substantially equivalent to the predicate device as described herein in.