



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Dexcowin Co., Ltd.
% Ms. Joyce St. Germain
Regulatory Department Manager
100 East Granada Blvd., Suite 219
ORMOND BEACH FL 32176

October 26, 2017

Re: K173046
Trade/Device Name: Cocoon Portable Handheld X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: September 26, 2017
Received: September 28, 2017

Dear Ms. St. Germain:

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 yours,

 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

Indications for Use

510(k) Number (if known)

K173046

Device Name

Cocoon Portable Handheld X-ray system

Indications for Use (Describe)

Cocoon is a portable X-ray System indicated for taking diagnostic dental x-rays for both pediatric and adult patients using intraoral film or digital sensors.

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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510k FDA Consulting

Medical Device Clearance

100 East Granada Blvd., Suite 219

Ormond Beach, FL 32176

386-506-8711

Special 510(k) Summary / K173046

Submitter/Applicant

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September 26, 2017

Preparer/Consultant

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Device Classification

Trade Name:	Cocoon Portable Handheld X-ray system
Common Name:	Portable x-ray System
Regulation Name:	Extraoral Source X-ray System
Regulation Number:	21 CFR 872.1800
Primary Product Code	MUH
Regulatory Class:	II
510k Review Panel:	Dental

Predicate Device

The following predicate was cleared as a Special 510k to the original (K083532) reference predicate.

The following predicate is a legally marketed, post-amendment device:

510(k) Number:	K133007
Date Cleared:	April 24, 2014
Device Name:	DX-3000 Portable X-ray System
Common Name:	Portable X-ray System
Regulation Name:	Extraoral Source X-ray System
Regulation Number:	21 CFR 872.1800
Primary Product Code:	MUH
Regulatory Class:	II
510k Review Panel:	Dental

Reference Predicate

510(k) Number:	K083532
Clearance Date:	March 10, 2009
Device Name:	ADX4000-L, DX3000-L
Common Name:	Portable X-ray System
Regulation Name:	Extraoral source X-ray System
Regulation Number:	21 CFR 872.1800
Regulatory Class:	II
Primary Product Code:	MUH

Indications for Use

Cocoon is a portable X-ray System indicated for taking diagnostic dental x-rays for both pediatric and adult patients using intraoral film or digital sensors.

Intended Use

The Cocoon device is intended for use in dental radiographic examination and diagnosis of the teeth, jaw, and oral structure for both pediatric and adult patients.

Device Description

Cocoon Portable X-ray System from Dexcowin Co., Ltd., of Seoul, Korea is a handheld x-ray device. The technology of this device was originally developed in Korea more than a decade ago and global production is still concentrated in that country.

The subject device is designed for dental radiographic examination and diagnosis

of diseases of the teeth, jaw, and oral structure by exposing an x-ray image receptor to ionizing radiation. The x-ray source, a tube, is located inside the handheld device. All three conventional types of intraoral receptors can be used with this device—analog x-ray film, digital phosphorous plates, and digital x-ray sensors.

Comparison of Technological Characteristics with Predicate

The following table compares technological and other characteristics of the subject and predicate device.

**Table 5 -- Technological Comparison
Subject Models: DX-7017 and DX-7020**

Feature	Cocoon (Subject Device) DX-7017 / DX-7020 K173046	Dexcowin DX3000 (Predicate K133007)	Dexcowin DX3000-L (Predicate K083532)
Intended Use	Indicated for taking diagnostic dental x-rays for both pediatric and adult patients using intraoral film or digital sensors.	Indicated for taking diagnostic dental x-rays for both pediatric and adult patients using intraoral film or digital sensors.	Indicated for taking diagnostic dental x-rays for both pediatric and adult patients using intraoral film or digital sensors.
Mechanical			
Size : Body	7.6"(H)×5.2"(W)×10.6"(D)	5.5"(H)×6.5"(W)×3.2"(D)	5.5"(H)×6.5"(W)×3.2"(D)
Weight	5.0 lbs. (without battery)	4.4 lbs. (without battery)	4.4 lbs. (without battery)
Source to skin distance	180mm	200mm	200mm
Cone diameter	58mm	55mm	55mm

Exposure switch	On tube-head assembly, or at control panel	On tube-head assembly, or at control panel	On tube-head assembly, or at control panel
Tube head mounting	Handheld, or on a tripod	Handheld, or on a tripod	Handheld, or on a tripod
Electrical			
Energy Source	Rechargeable 16.8V DC Li-Polymer battery pack	Rechargeable 16.8V DC Li-Polymer battery pack	Rechargeable 16.8V DC Li-Polymer battery pack
Exposure Time	0.05~1.00 seconds in 0.001 increments	0.05~1.35 seconds in 0.005 increments	0.05~1.35 seconds in 0.005 increments
Timer Accuracy	$\pm(10\% + 1\text{ms})$	$\pm(10\% + 1\text{ms})$	$\pm(10\% + 1\text{ms})$
Tube Voltage	70kVp fixed for DX-7017 and DX-7020	60kVp fixed	60kVp fixed
Tube Current	1.7mA = DX-7017 2.0mA = DX-7020	2mA fixed	1mA fixed

The above comparison shows the subject and predicate devices have substantially the same technology characteristics.

The differences of the subject device are shown in blue highlights as compared to the predicate devices. The differences of the subject are due to design changes and the differences have all been tested according to ISO standards and have proven to be as safe and effective as the previous devices. The indications for use and the technological characteristics are the same in these devices and the subject device does not cause any new issues of concern.

All Standard Test Performed for the Subject Device Models: DX-7017 and DX-7020 are listed below:

Declaration of Conformity

- Council Directive 93/42/EEC as amended by 2007/47/EC of 14 June 1993 concerning medical devices
- MEDDEV 2.12-1 Rev.8 Guidelines on a medical device vigilance system

No	Standard	Application
1	EN ISO 13485:2012	Medical devices - Quality management systems - Requirements regulatory purposes(ISO 13485:2003) EN ISO13485:2003/AC:2007
2	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices(ISO14971:2012)
3	IEC 60601-1:2005 /AMD1:2012	Medical electrical equipment - part1: General requirements for basic safety and essential performance
4	IEC 60601-1-2:2007	Medical electrical equipment - Part1-2:General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
5	IEC 60601-1-3:2008	Medical electrical equipment - Part1-3: General requirements for basic safety essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment
6	IEC 60601-1-6:2010 /AMD1:2013	Medical electrical equipment-part1-6:General requirements for basic safety and essential performance-Collateral standard: Usability
7	IEC 60601-2-28:2010	Medical electrical equipment-part2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
8	IEC 60601-2-65:2012	Medical electrical equipment-part2-65:Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
9	IEC 62366-1:2015	Medical devices-part1: Application of usability

		engineering to medical devices
10	IEC62304:2015	Medical device software - software life cycle processes.
11	ISO 14155-1:2010	Clinical investigation of medical devices for human subjects
12	ISO 15223-1:2010	Medical devices: Symbols to be used with medical devices labels, labeling and information to be supplied
13	EN1041:2008	Information supplied by the manufacturer with medical devices
14	ISO 10993-1:2009	Biological evaluation of medical devices-Part1: Evaluation and testing within a risk management process
15	ISO 17050-1:2010	Conformity assessment-supplier's declaration of conformity - part 1:General requirements

Non-Clinical Performance Data

The following performance was completed on the subject device in support of the substantial equivalence determination.

- Electrical Safety and EMC
- Specifications of Raw Material
- Software Validation
- Biocompatibility
- Usability
- Clinical Comparison
- Risk Assessment

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- All tests were performed in accordance with ISO standards and recognized by FDA.
 - None of the standards was adapted for application to the device under review.
 - There were no requirements of any standard that were not applicable to the device.
 - No deviations from the standards were applied.

- No differences exist between the tested device and the device to be marketed.
- Conformity with all standards was determined by the device manufacturer, Dexcowin Co., Ltd., Korea.
- Electrical test performed by Met Laboratories, Inc.

Specific Guidance Document

There is a FDA Specific Guidance Document associated with the device: *Radiation Safety Consideration for X-ray Equipment Designed for Hand-Held Use*. This submission utilized this guidance to develop this device to ensure the safety of this device for both the operators and the patients.

Labels

The labels on the device show that this device conforms to the following:

21 CFR 1020 Subchapter J: Performance Standards for Ionizing Radiation Emitting Products,
21 CFR 1020.30: Diagnostic x-ray systems and their major components,
21 CFR 1020.31: Radiographic Equipment

Conclusion

The Cocoon Portable X-ray System shows substantial equivalence to its original predicate and modified predicate devices. All differences were evaluated according to the tests and deemed not to raise new issues of safety or effectiveness. The modifications did not affect the device's intended use or alter the device's fundamental scientific technology. **This modified subject device is at least as safe and effective as the predicate devices.**