October 24, 2025

Dexcowin Global Inc
% Dave Kim
Regulatory Affairs Consultant
Mtech Group LLC
7505 Fannin St. Suite 610
HOUSTON, TX 77054

Re: K250687
Trade/Device Name: Cocoon Solo (DX-7020s)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: September 26, 2025
Received: September 26, 2025

Dear Dave Kim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Digitally signed by Gabriela M. Rodal -S for

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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250687

Device Name
Cocoon Solo (DX-7020s)

Indications for Use *(Describe)*

Cocoon Solo (DX-7020s) is a portable x-ray system indicated for taking diagnostic dental x-rays for both pediatric and adult patients.

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

K250687

The following 510(k) summary is being submitted as required by 21 CFR 868.5120;

1. Submitter:

Dexcowin Global Inc.
Office # 878 Regus Center 155
Lake Ave., Suite 800
Pasadena, CA 91101

Manufacturer:

Dexcowin Co., Ltd.
905, 2, Gasan digital 1-ro, GeumCheon-Gu
Seoul, Republic of Korea 08591
82-2-2027-2880
Ryu, Seung-Bum (sbryu@dexcowin.com)

Contact Person: (Official Correspondent)

Mtech Group LLC
Dave Kim, MBA
7505 Fannin St. Suite 610, Houston, TX 77054, US
Tel: 713-467-2607
Email: davekim@mtechgroupllc.com

Date Prepared: September 25, 2025

2. Device Identification

Device Trade Name	Cocoon Solo (DX-7020s)
Common Name	Portable X-ray System
Classification Number	21 CFR 872.1800
Device Classification	Extraoral source x-ray system
Regulation Name	II
Product Code	MUH

3. Predicate Device

Device Trade Name	Cocoon [DX-7017 / DX-7020]
510K Number	K173046
Common Name	Portable X-ray System
Classification Number	21 CFR 872.1800
Device Classification	II
Product Code	MUH

4. Device Description

Cocoon Solo (DX-7020s) is a handheld, portable X-ray device designed for dental radiographic examination and diagnosis for pediatric and adult patients by exposing a X-ray image receptor to ionizing radiation.
The X-ray tube is located inside the device body to be used with conventional film (F-speed or greater film), PSP (Phosphor plates), or digital X-ray sensors.

The image detectors (an integral part of a fully-functional diagnostic x-ray system) are not part of the submission.

This device should only be used by trained and qualified dentists or dental technicians.

The subject device Cocoon Solo (DX-7020s) is strongly based on the predicate (from the same manufacturer). Changes to the predicate device are only minor and they don't seem to affect device safety or effectiveness.

5. Indications for Use

Cocoon Solo(DX-7020s) is a portable x-ray system indicated for taking diagnostic dental x-rays for both pediatric and adult patients.

6. Non-clinical Performance Test

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
- Risk Assessment
- 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 deviation from the standards applied.
- No difference exist between the subject device and the sample test device unit.

Bench Testing for Image Performance has not been performed because the changes from the predicate system are only minor and the x-ray detectors are not part of the submission. The image quality should stay unchanged from the predicate performance.

7. Safety, EMC Data

Cocoon Solo(DX-7020s) complies with industry standards such as IEC 60601-1 Series to minimize electrical, mechanical and radiation hazards.

• Electrical, mechanical, environmental safety and performance testing which are mentioned in the standard IEC 60601-1, IEC 60601-1-3 and IEC 60601-2-65 were performed.
• EMC testing was conducted in accordance with Standard IEC 60601-1-2
• Performance testing performed according to FDA 21CFR 1020.30, 21CFR 1020.31 standards, Software Validation.

FDA Specific Guidance Documents associated with the device:

• Radiation Safety Consideration for X-ray Equipment Designed for Hand-Held Use.
• Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff "
• Pediatric Information for X-ray Imaging Device Premarket Notifications - Guidance for Industry and Food and Drug Administration Staff".
• Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions - Guidance for Industry and Food and Drug Administration Staff ."

All test results were satisfied

8. Clinical Test Conclusion

Clinical testing was not required for this submission.

9. Technical Characteristics and Substantial Equivalence

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

Table 1. General Device Characteristics Comparison Table

	Candidate Device	Predicate Device		Substantial Equivalence Analysis
510(k) Number	K250687	K173046		-
Device Name	COCOON SOLO (DX-7020s)	COCOON		-
Manufacturer	Dexcowin Co., Ltd	Dexcowin Co., Ltd.		-
Product Code	MUH	MUH		-
Indication for Use	Cocoon Solo(DX-7020s) is a portable x-ray system indicated for taking diagnostic dental x-rays for both pediatric and adult patients	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.		Substantial Equivalence
Tube Voltage	70kV (fixed)	70kV (fixed)		Substantial Equivalence
Tube Current	1.7mA/2.0mA (fixed)	2.0mA (fixed)		Substantial Equivalence
Exposure Time	0.05 – 1.00 seconds	Same		Substantial Equivalence
Focal Spot	X-ray tube(D-041): 0.4 mm	X-ray tube (D-041)	0.4mm	Substantial Equivalence
		X-ray tube (DXDR-070)	0.3mm	
Total Filtration	2.3 mmAl (Inherent Filtration: 1.0mmAl)	X-ray tube(D-041)	2.2 mmAl (Inherent Filtration: 1.0mmAl)	Substantial Equivalence
		X-ray tube(DXDR-070)	2.62 mmAl (Inherent Filtration: 1.82mmAl)	
SSD	180mm	Same		Substantial Equivalence
Cone Diameter	58mm	Same		Substantial Equivalence
Weight	5 lbs	4 lbs		Substantial Equivalence
Detector Compatibility	Film/Digital Sensor/PSP	Same		Substantial Equivalence
Power Supply	16.8 Vdc Li-Polymer rechargeable battery	Same		Substantial Equivalence

The subject device and predicate device have no significant differences in most parameters and the differences do not affect the substantial equivalence of the subject device when compared to the predicate device.

10. Conclusion

The Cocoon Solo (DX-7020s) shows substantial equivalence to the predicate device. 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.