DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	2/20/2023-2/23/2023
	FEI NUMBER 3007065358

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sung-Hyun Park, Quality Manager

FIRM NAME	STREET ADDRESS
Dexcowin Co. Ltd.	901~905 25 Gasan digital 1-ro
CITY, STATE, ZIP CODE, COUNTRY Geumcheon-gu, Seoul, 08594 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

Your firm received a complaint via email on September 14, 2019, alleging that two of your Class II portable x-ray devices, the Cocoon - models DX-7017 and DX-7020:

1)May be incorrectly labeled as one device contained a removable label over the permanently affixed model label.
2)Did not clearly indicate the focal spot for the skin-source distance as the sticker indicating the focal spot was removable.
3)Had highly variable entrance skin exposure values - ~26% for the device identified as DX-7017 and ~48% for the device identified as DX-7020.

This complaint was not analyzed and recorded in your Customer Complaint and Handling Ledger, F709-1, as required by Section 5 of your complaint handling procedure, Customer Complaint Management, QP-801, Revision 5. Additionally, Section 4.1 of your complaint handling procedure requires complaints

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Alexandria L Capuano, Investigator	X Alexandria L Capuano Investigator Signed By: Alexandria L. Capuano Date Signed: 03-23-2023 20:07:45	2/23/2023

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Sung-Hyun Park, Quality Manager	
FIRM NAME Dexcowin Co. Ltd.	STREET ADDRESS 901~905 25 Gasan digital 1-ro
CITY, STATE, ZIP CODE, COUNTRY Geumcheon-gu, Seoul, 08594 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED Manufacturer

about products to have a request filled out for corrective and preventive action, which was not done. Your firm's quality manager confirmed that this complaint was not added to your RMA/Complaint logbook (the Customer Complaint and Handling Ledger, F709-1) since it was for a demo unit and not a customer complaint. When asked were records of this complaint and its communication were maintained, your firm's GM stated that the emails were kept in a folder in the email application.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Alexandria L Capuano, Investigator	X Alexandria L Capuano Investigator Signed By: Alexandria L. Capuano Date Signed: 02-23-2023 20:57:45	2/23/2023

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Annotations to Observations

Observation 1:

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."