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	5/20/2024-5/23/2024
	FEI NUMBER 3012855798

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Anthony J. Skeats, Chief Operating Officer	
FIRM NAME Micro-X Ltd.	STREET ADDRESS Unit 14 6 MAB Eastern Promenade
CITY, STATE, ZIP CODE, COUNTRY Tonsley, South Australia, 5042 Australia	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

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, the firm failed to report the following field corrections conducted to reduce a risk to health posed by Micro-X Rover Mobile X- ray Systems:

Service Bulletin, SB003-23 is issued to inform of a Micro-X Rover RV-35 firmware update addressing improvements to the software when exposing short pulse exposures. The documented risk is described as “there is a low probability that a Critical Error is reported to the operator during radiation exposures of a short pulse duration”. “If this Error is reported, a repeat exposure at different exposure techniques may be required to obtain necessary diagnosis”.

Service Bulletin for the Micro-X Rover, SB002-22 is issued to inform of a field upgrade for the installation of an exposure switch holder on the Rover Mobile X-ray Units. The exposure switch holder attachment is to reduce the probability of the exposure button being pressed inadvertently while stored.

Service Bulletin, SB006-23 for Micro-X Rover RV19, Micro-X Rover RV35 and Micro-X Rover RV80 is issued to inform of the correct process to switch between User profiles to reduce the risk of the on-

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	Maryam Tabatabaie, Investigator X Maryam Tabatabaie Investigator Signed By: Maryam Tabatabaie -S Date Signed: 05-23-2024 13:05:16	5/23/2024

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screen keyboard inaccessibility and to ensure that when any service / administrator work is performed, the on-screen keyboard will be accessible in other User profiles. The risk associated with not performing the described process outlined in the Bulletin includes the on-screen Keyboard is not accessible in User profile, not possible to enter patient data, unable to annotate images with text, and unable to configure the system with text.

Service Bulletin, SB007-23-1.0 is issued for Micro-X Rover to notify about the use of the Rover product in extreme humidity environments which can adversely affect the equipment, impact the performance and integrity of the product. The risks associated with not performing the procedures outlined in the bulletin includes capacitors within the capacitor bank malfunctioning, unpredictable system behavior may occur as a result, the system may cease to function all together, overheating could cause damage to control boards, and there is a risk of unintended start-up behavior during these scenarios.

Modification 017 for Micro-X Rover RV35, and Micro-X Rover RV71 is to announce that at 70 kv 80mAs, the Rover can report and deliver a lower post exposure mAs value than what set by the operator. The tertiary exposure timer was being initiated due to a longer than expected preparation time of the upper-level system. According to the Bulletin, this modification is required for Rover model variants operating with the Micro-X Generator, P# 16705-12 and earlier revisions. The replacement of the Control Board PCBA, 12425-03 (or earlier) with Control Board PCBA, 12425-04 will eliminate the issue. The risk is documented as increase to filtering that increases RC time-constant which may cause the firmware to flag errors at the start of an exposure.

OBSERVATION 2

Procedures for design change have not been established.

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Specifically, Design Change Control procedure, SOP002 and Design Change Management -Medical Devices, WI002A are not adequately established to ensure that all product design changes are processed and documented according to these procedures. Instead, the design changes to address nonconforming products identified during manufacturing are documented using Manufacturing Deviation, SOP025. The review of the manufacturing deviation records revealed that the design changes implemented as Manufacturing deviations are not adequately evaluated and verified/ validated.

OBSERVATION 3

A process whose results cannot be fully verified by subsequent inspection and test has not been validated according to established procedures.

Specifically, the manufacturing process for Micro-X Rover RV71 that is marketed and distributed in the US has not been validated. The firm was unable to provide a documented justification for the decision not validate.

OBSERVATION 4

Procedures for corrective and preventive action have not been adequately established.

Specifically, Quality Event and CAPA procedure, SOP006 does not ensure that 1) sources of quality data are adequately analyzed to identify existing and potential causes of nonconforming product or other quality problems. 2) the firm failed to adequately identify the corrective actions for CAPA040-23 involving a reported malfunction of Rover Model: RV35.

OBSERVATION 5

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

Specifically, the complaints of reported malfunctions of the Micro-X Rover Mobile X-ray Systems are

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not adequately evaluated for MDR reporting. The rationale for the decision not to report is not documented as for example, in the case of the following complaints: CC022-23, CC017-23, CC004-23, and CC010-23.

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

Observation 5:

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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."