Records processed under FOIA request 2018-6794; Released on 05/30/2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301) 594-4695 FAX: (301) 594-4715 Industry Information: www.fda.gov/oc/industry	07/09/2018- 07/12/2018
	FEI NUMBER 3001319476

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Philip Hung, Project Manager

FIRM NAME	STREET ADDRESS
Modern Medical Equipment Manufacturing LTD	Dong Xing Industrial Area, Kang Le Lu, Shan Xia District
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hengli, Dongguan Guangdong China 523460	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.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

Your firms complaint record, (b)(4), opened on 05/31/2018, related to a customer reporting a device malfunctioning (pencil tip remained in contact with the patient's face "...generating burn risks") did not include an adequate investigation. For instance, your firm did not follow up with the customer to obtain additional information in order to conduct an adequate MDR determination; there was no assessment of other potentially affected units in the field, and the risk analysis was not reviewed.

am 7/12/18

Observation 2

CAPA records are inadequate in that CAPAs opened during last FDA Inspection were not Fully addressed

(a). CAPA13-002, CAPA14-001, and CAPA 14005 were opened due to workmanship issues; however, there's no acknowledgement in the records that there are other CAPAs with the same problem.

(b). CAPA13-03001 did not include ensuring (b)(4) verification included the total number of electrosurgical pencils (b)(4) that can be dried at once.

Observation 3

Your stability studies covering the disposable general electrode did not cover the complete environmental conditions listed in the product labeling, nor did you provide justification for not needing to verify functionality of the device at the full range of conditions listed on the label.; Furthermore, accelerated testing records did not include the humidity conditions used.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Ashley A. Mutawakkil	Ashley A. Mutawakkil, Investigator	07/12/2018

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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STREET ADDRESS
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CITY, STATE AND ZIP CODE
Heng Li, Dongguan Guangdong China 523466

TYPE OF ESTABLISHMENT INSPECTED
Manufacturer

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Observation 4

Simulation testing conducted during design validation of the disposable electrode was not conducted on porcine kidney and liver as reported to FDA in the 510(k) submission. Furthermore, it was not done according to a preapproved plan.

Observation 5

Your firm did not document design outputs in a manner that allows adequate evaluation of conformance to design input requirements for the disposable electrode design project.

Observation 6

Design inputs for the disposable electrode design project are incomplete in that performance characteristics and labeling requirements were not documented for example. Furthermore, the design inputs document references another document, Product Matrix of Disposable Blade Electrode, which was not provided.

Add Continuation Page

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	Ashley A. Matawalski	Ashley A. Matawalski, Investigator	07/12/2018

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STREET ADDRESS
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CITY, STATE AND ZIP CODE
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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Annotations:

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Blank

Observation 5: Promised to correct

Observation 6: Promised to correct

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	Ashley A. Mutawakil	Ashley A. Mutawakil Investigator	07/12/2018

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