DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707 oradevices1firmresponse@fda.hhs.gov	10/25/2021-10/28/2021
	FEI NUMBER 3011654983

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christina M. Craigo, General Manager

FIRM NAME	STREET ADDRESS
HG Medical USA, LLC	810 Memorial Blvd
CITY, STATE, ZIP CODE, COUNTRY Huntington, WV 25701-7002	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

Records of acceptable suppliers and contractors have not been adequately established.

Specifically,

Your firm failed to adequately approve critical suppliers of components and services without a quality management system listed on your approved supplier list. For example:

1. Your critical supplier, who you purchase your endotoxin tester used during passivation of (b) (4), failed to have the required audit conducted by your firm.

2. Your critical supplier, who you purchase your (b) (4) used during manufacturing of (b) (4), failed to have the required audit conducted by your firm.

3. Your critical supplier, who services your water treatment supply for (b) (4) water used during passivation of (b) (4), failed to have the required audit conducted by your firm.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tiki Dixon, Investigator X Tiki Dixon Investigator Signed By: 2000441527 Date Signed: 10-28-2021 11:00:56	10/28/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707 oradevices1firmresponse@fda.hhs.gov	10/25/2021-10/28/2021
	FEI NUMBER 3011654983

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Christina M. Craigo, General Manager	
FIRM NAME HG Medical USA, LLC	STREET ADDRESS 810 Memorial Blvd
CITY, STATE, ZIP CODE, COUNTRY Huntington, WV 25701-7002	TYPE ESTABLISHMENT INSPECTED Manufacturer

4. Your critical supplier, who services your passivation equipment used during passivation of (b) (4) , failed to have the required audit conducted by your firm.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tiki Dixon, Investigator X Tiki Dixon Investigator Signed By: 2000441527 Date Signed: 10-28-2021 11:00:56	10/28/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707 oradevices1firmresponse@fda.hhs.gov	10/25/2021-10/28/2021
	FEI NUMBER 3011654983

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christina M. Craigo, General Manager

FIRM NAME	STREET ADDRESS
HG Medical USA, LLC	810 Memorial Blvd
CITY, STATE, ZIP CODE, COUNTRY Huntington, WV 25701-7002	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tiki Dixon, Investigator X Tiki Dixon Investigator Signed By: 2000441527 Date Signed: 10-28-2021 11:00:56	10/28/2021

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."