DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	4/28/2026-4/30/2026
	FEI NUMBER 3007304202

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joseph A. Grohowski, President

FIRM NAME	STREET ADDRESS
Praxis Powder Technology, Inc.	604 Queensbury Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Queensbury, NY 12804-7618	Medical Device Contract 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

Requirements for infrastructure maintenance activities that can affect product quality, including the interval of performing the maintenance activities, have not been adequately documented.

Specifically, 2 of 10 (b) (4) preventive maintenance records reviewed for the sintering furnace with equipment number (b) (4) documented that the preventive maintenance was completed more than two weeks after the due date while continuing to use the sintering furnace in the manufacture of medical devices without documented rationale as required by Equipment Maintenance Program, QP-00054, Revision 11. The sintering furnace with equipment number (b) (4) is used in validated sintering processes performed during the manufacture of all finished devices manufactured by the firm.

OBSERVATION 2

Corrective action procedures defining the requirements for planning and documenting action needed and implementing such action and reviewing the effectiveness of corrective action taken have not been adequately documented.

Specifically, 1 of 6 corrective actions reviewed did not include corrective actions fully addressing the identified root cause or an adequate effectiveness check. In addition, 1 corrective action reviewed did not include an adequate effectiveness check as it did not include justification of the adequacy of the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Matthew D Schnittker, Investigator X Matthew D Schnittker Investigator Signed By: Matthew D. Schnittker -S Date Signed: 04-30-2026 09:13:55	4/30/2026

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effectiveness check plan as required by Corrective Action and PReventive Action, QP-00038, Revision 13.

OBSERVATION 3

One or more processes for risk management in product realization have not been adequately documented.

Specifically, Risk Management, QP-00036, Revision 5 does not include a clear requirement to identify harms to end users or patients associated with identified failure modes. Additionally, the risk assessment documented for processes related to medical devices that are manufactured using titanium metal injection molding does not identify the harms associated with the identified failure modes and does not include a review of controls for the opportunity to lower risk further for failure modes with a mid risk level as required by Risk Management, QP-00036, Revision 5.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

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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."