**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1777 Hardee Ave SW<br>Atlanta, GA 30310<br>(404)253-1284 Fax:(404)669-4443 | 5/18/2026-5/21/2026 |
| | FEI NUMBER<br>1000165286 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tera A. Laken, General Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| Biomerics Precision Concepts Group | 3735 Kimwell Dr |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Winston Salem, NC 27103-6705 | 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 OBSERVED:**

## OBSERVATION 1

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

Specifically, your firm failed to document in the (b) (4) Process PFMEA, W-09-3018, Revision B, the process function for controlled storage requirements of the Class II (b) (4) Blister Pack containing a (b) (4). The Internal Corrective Action Report, ICAR-0049, opened on 10/01/2025 for the temperature data missing for the data logger did not evaluate if the process should be added to the PFMEA. Furthermore, your firm failed to maintain the Temperature Data Logger, Model (b) (4), Equipment ID: PCG-AS3-0271, in the sensitive storage area with the correct time of day and to verify the temperature ranges were maintained for the storage of the (b) (4) Blister Packages.

## OBSERVATION 2

Procedures for timely complaint handling have not been adequately documented.

Specifically, your firm failed to document in the Customer Complaint Management Procedure, P-01-0021, Rev D, dated 9/24/2025, the requirements needed in a complaint form for investigation of the complaint, list of any correction or corrective action resulting from the complaint handling process, determining the need to report the information to the appropriate regulatory authorities, a justification documented if any complaint is not investigated, and a complaint closure date documented. In my review of the Class II medical device (b) (4) complaint records CCAR-0250, CCAR-0277, and CCAR-0298, the complaint records did not capture all required information listed and were not documented on an approved customer complaint record form.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Christopher B May, Investigator<br>X Christopher B May Investigator Signed By: CHRISTOPHER B. MAY -S Date Signed: 05-21-2026 13:38:11 | 5/21/2026 |

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Investigator
Signed By: CHRISTOPHER B. MAY -S
Date Signed: 05-21-2026
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## Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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Christopher B May, Investigator

X Christopher B May Investigator Signed By: CHRISTOPHER B. MAY -S Date Signed: 05-21-2026 13:38:11

DATE ISSUED
5/21/2026

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."