DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	2/18/2026-2/26/2026* FEI NUMBER 3021680161

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
David Y. Burke, Prnciple/Owner	
FIRM NAME	**STREET ADDRESS**
Bear-Ent, Llc	274 Lancaster Ave Ste 208
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Malvern, PA 19355-3255	Medical Device 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 risk management activities in product realization were not maintained.

Specifically, Risk Management Procedure, SOP - 04, Version No. 001, requires the implementation of a risk management process and the required risk management activities. For example, the following specified requirements per the procedure have not been established: Risk Management Plan, Risk Assessment, Risk Management Report, and a Risk Management File.

OBSERVATION 2

Complaint handling records were not maintained.

Specifically, Customer Feedback Procedure, SOP-13, Version No. 001, Section 6.2, Complaint Handling, defines complaints that allege deficiencies related to the identity , quality, durability, reliability, safety, effectiveness, or performance of a medical device after it is released for distribution. During the inspection, management stated that they do not process any customer complaints unless the complainant describes an injury and/or death. For example, management stated that they have received customer complaints about broken, rusting, pitting and dirty surgical instruments distributed to customers, but never document these types of complaints per the procedure.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edward D Mcdonald, Investigator	X Edward D Mcdonald Investigator Signed By: Edward D. Mcdonald - S Date Signed: 02-26-2026 12:23:11	2/26/2026

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OBSERVATION 3

Records of the results and conclusion of validation of processes and necessary actions from the validation were not maintained.

Specifically, Master Validation Procedure, SOP - 16, Version No. 001, requires the qualification and validation of manufacturing processes. The ultrasonic cleaning process for surgical instruments has not been validated to assure the cleaning process meets defined requirements. For example, the (b) (4) (b) (4) has not been qualified in accordance with the SOP. No established operational specifications for time, temperature and power have been documented.

OBSERVATION 4

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

Specifically, the (b) (4) water system used to provide water to the ultrasonic cleaners used for cleaning of surgical instruments prior to packaging and labeling has no requirements for maintenance activities. For example, there are no specifications for the (b) (4) water system (b) (4) and no established requirements for (b) (4) maintenance. There are no established procedures or work instructions for the use and maintenance of the (b) (4) water system.

OBSERVATION 5

Records of the results of evaluation, selection and monitoring of supplier capability or performance were not maintained.

Specifically, Supplier Evaluation Procedure, SOP-05, Version No. 001 has not been implemented. For example, Section 6.2, Evaluating Supplier Performance, requires the (b) (4) evaluation for critical suppliers and (b) (4) for non-critical suppliers. The supplier evaluations are required to be documented using the (b) (4) per the procedure. No (b) (4)

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(b) (4) were available for any product suppliers.

OBSERVATION 6

Records from management review were not maintained.

Specifically, Management Responsibility and Review Procedure, SOP-02, Version No. 001, requires (b) (4) management reviews per section 6.4, Management Review. No management reviews have been conducted in 2023, 2024 and 2025.

OBSERVATION 7

Internal audits have not been conducted at planned intervals to determine whether the QMS.

Specifically, Internal & Supplier Audit Procedure, SOP - 22, Version No. 001, states in Section 6.1, Audit Schedule, requires the performance of (b) (4) internal audits. (b) (4) audits are conducted per the audit schedule which is recorded on (b) (4) as required in Section 5, Related Items. No internal audits or audit schedules have been completed for 2023, 2024, and 2025.

***DATES OF INSPECTION**

2/18/2026(Wed), 2/19/2026(Thu), 2/26/2026(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edward D Mcdonald, Investigator	X Edward D Mcdonald Investigator Signed By: Edward D. Mcdonald - S Date Signed: 02-26-2026 12:23:11	2/26/2026

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Annotations to Observations

Observation 1: Promised to correct by 06/01/2026

Observation 2: Promised to correct by 06/01/2026

Observation 3: Promised to correct by 06/01/2026

Observation 4: Promised to correct by 09/01/2026

Observation 5: Promised to correct by 09/01/2026

Observation 6: Promised to correct by 09/01/2026

Observation 7: Promised to correct by 09/01/2026

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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."