DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	5/26/2026-6/1/2026* FEI NUMBER 1000518793

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Erin M. Hickey, President

FIRM NAME	STREET ADDRESS
Bioplate Inc	570 S Melrose St
CITY, STATE, ZIP CODE, COUNTRY Placentia, CA 92870-6327	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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Records of risk management activities in product realization were not adequately maintained.

1. Specifically, during the inspection, the following records were reviewed: D00383 Rev C (DFMEA for Manufacture of Bioplate Screws), D00382 Rev B (DFMEA for Bioplate Plates and Mesh), DD00389 Rev B (PFMEA for Manufacture of Bioplate Screws), and SOP-0016 Rev C (Risk Management Procedure). Review of these records identified the following deficiencies:

   D00383 Rev C — DFMEA for Manufacture of Bioplate Screws:

a) 38 (contact of implant with meninges) carries a Severity rating of (b) (4) (Catastrophic) and a Final Risk score of (b) (4) Per SOP-0016 §6.8.4 and the firm's risk matrix at §6.8.4.3, a score of (b) (4) falls within the Unacceptable (UNACC) zone. Per SOP-0016 §6.13.2, this rating requires that the design process be reevaluated before implementation. No evidence of design reevaluation was found in the record. Additionally, SOP-0016 §6.10 requires a documented risk/benefit analysis when residual risk cannot be further reduced; no such analysis was present for Row (b) (4)

b) Rows (b) (4) list IFU warnings or contraindications as the primary or sole risk control, and several of these rows record a reduction in Failure Probability (FP) attributable to that control. SOP-0016 §6.9.2 states that information for users, such as warnings and cautions, "DOES NOT REDUCE the risk in and of itself," and §6.9 requires that design-level controls be exhausted prior to reliance on labeling. No

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documentation was provided to demonstrate that design-level controls were evaluated and found infeasible for these rows prior to the use of labeling as the primary control.

c) Multiple rows reference "Release of final design specifications" as a risk control or mitigation. When asked, the firm (Quality & Regulatory Affairs Manager) stated verbally that this phrase refers to a requirement to assess the design for changes. This meaning is not apparent from the language used in the document.

DD00389 Rev B — PFMEA for Manufacture of Bioplate Screws:

d) No process step for sterilization is included in the PFMEA. The document references a companion record (D00393) for sterile finished goods; however, no boundary statement or explicit handoff notation is present to identify where sterilization risk controls are addressed and to establish traceability between the two documents.

e) No process step for packaging integrity is included. Packaging failure modes (e.g., seal integrity, container closure) were identified in the DFMEA (Rows (b) (4)); no corresponding manufacturing-level control for these failure modes appears in the PFMEA.

f) No process step for cleaning or decontamination of machined screws prior to secondary processing or packaging is included. Foreign matter contamination was identified as a failure mode in the DFMEA (Row (b) (4)). Additionally, the firm received complaints #23-001 and #23-003 for contamination of sterile product, with root cause identified as excess material from the sterile kit base resulting from insufficient (b) (4) cleanup by the supplier. No corresponding manufacturing control for cleaning appears in the PFMEA.

g) No process step addresses labeling accuracy, lot or batch identification, or traceability controls during manufacturing. The firm produces a multi-diameter, multi-series product line for which lot mixing and labeling errors are foreseeable process-level failure modes. SOP-0016 §7

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requires (b) (4) review of risk management records against post-market data. The DFMEA (D00383 Rev C) contains no evidence of post-market data review since 2017.

OBSERVATION 2

Procedures for the feedback process have not been adequately documented to include provisions for gathering data from production and post-production activities.

1. Specifically, during the inspection, the following records were reviewed: (b) (4) management review records for [Quality System Management Review dated 10/01/25 and 03/25/2026], and risk management records for the Bioplate Neurosurgical Line. Review of these records identified the following:

   a) The (b) (4) management review records for 2025 did not include an analysis of complaint data for trends, CAPA status, or process and product performance. I reviewed your complaint log and for 2025 you had 11 each complaints.

   b) The risk management records for the Bioplate Neurosurgical Line were last updated in 2017 as noted by your risk management reports revision history. No evidence was provided that post-production data, including complaint data, has been incorporated into risk management records since that date.

OBSERVATION 3

Outsourced processes that affect product conformity to requirements were not adequately monitored and controlled.

Specifically, during the inspection, the following records were reviewed: purchase orders for outsourced manufacturing of Bioplate Neurosurgical screws, the firm's approved supplier list, and Quality Agreement Doc #F00514 Rev B with (b) (4). The following was observed:

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The firm has outsourced manufacture of Bioplate Neurosurgical screws to the supplier referenced above. Purchase orders totaling (b) (4) parts were identified from 2023 to the present. The supplier is classified as a Class (b) (4) (critical) supplier of implantable neurosurgical screws in the firm's supplier qualification records.

a) The supplier does not have a documented quality management system as noted on their supplier assessment form dated 01/31/25.

b) No on-site audit of this supplier has been conducted since 2010 as noted as recorded on your "Supplier Onsite Quality Questionnaire dated 09/17/2010".

c) The Quality Agreement between Bioplate and (b) (4) (Doc #F00514 Rev B) contains the following specific deficiencies:

- Sections 7 through 9, which address quality system requirements, are marked N/A. No documented rationale for this designation was provided.
- Appendix A, which is designated to identify the products and services covered by the agreement, is blank. The scope of the agreement is therefore undefined.
- Section 29.1, which addresses record retention, does not specify a retention period.
- Section 10.0, which addresses risk management per ISO 14971, is marked N/A for a supplier classified as critical and providing finished device components. No documented rationale for this designation was provided.

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- The agreement does not define incoming inspection requirements or acceptance criteria for product received from this supplier.
- The agreement does not establish performance metrics, rejection rate thresholds, or conditions that would trigger re-evaluation of the supplier outside the frequency defined in SOP-0047.

OBSERVATION 4

Corrective action procedures defining the requirements for reviewing nonconformities, determining the causes of nonconformities and evaluating the need for action to ensure that nonconformities do not recur have not been adequately documented.

Specifically, during the inspection, complaint files from 2023 to the present and CAPA records for the same period were reviewed, along with SOP-0010 Rev H (Corrective and Preventive Action). The following was observed:

d) A total of 30 complaints were recorded from 2023 to the present. Of these, 14 (e.g. 25-001, 25-004, 25-009)(46.7%) are associated with issues involving implantable screws and blades of the - Bioplate Neurosurgical line. No CAPA was opened in response to this complaint trend.

e) Review of SOP-0010 identified the following deficiencies in the documented CAPA procedure:

- The SOP does not include a requirement to evaluate whether a proposed corrective action could adversely affect the ability to meet applicable regulatory requirements or compromise device safety and performance.
- The SOP does not include procedural steps for identifying, sourcing, or initiating preventive actions.

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- The SOP defines CAPA initiation in a manner that does not include all qualifying data sources. ISO 13485 §8.5.2 requires that CAPA procedures address nonconformities identified from complaints, audits, nonconforming product, servicing records, and process data. "The SOP states typically through MRB or Management Review and managed by the CAPA Administrator"
- The SOP does not include a requirement to trigger revalidation when a corrective action involves a change to a sterilization process, packaging process, or cleanroom procedure.
- The SOP requires risk analysis for product-related CAPAs but does not establish any differentiated requirements for CAPAs involving sterility failures or sterility-related process changes for implantable devices.

OBSERVATION 5

Planning of product realization was not consistent with the requirements of other quality management system processes.

Specifically, during the inspection, the following records were reviewed: installation qualification and validation records for manufacturing equipment at the firm's current facility, [Report No. TR-0384 Installation and Performance Qualification of Model (b) (4) (b) (4)(b) (4)) for NuVasive Attrax ; Report No. TR-0386 Installation & Performance Qualification of (b) (4) Heat Sealer (b) (4)) for NuVasive Attrax and Report No. TR-0387 Installation & Performance Qualification of (b) (4) Heat Sealer (b) (4)) for NuVasive Attrax], and process validation records for the Attrax Line of medical devices. The following was observed:

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a) In 2021, the firm relocated contract manufacturing operations for the Attrax Line to its current address. Installation qualification and operational qualification records for manufacturing equipment were available for review. However, no process validation records were available to demonstrate that the manufacturing process including sterilization preparation and verification that the firm performs were validated for this product line.

***DATES OF INSPECTION**

5/26/2026(Tue), 5/27/2026(Wed), 5/28/2026(Thu), 5/29/2026(Fri), 6/01/2026(Mon)

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Annotations to Observations

Observation 1: Under consideration

Observation 2: Under consideration

Observation 3: Under consideration

Observation 4: Under consideration

Observation 5: Under consideration

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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."