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	2/17/2026-2/27/2026* FEI NUMBER 3016171942

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen E Ryan, President

FIRM NAME	STREET ADDRESS
PROVISIO MEDICAL INC	10815 Rancho Bernardo Rd Ste 110
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92127-2187	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

Your firm did not adequately deal with nonconforming product detected prior to delivery by taking action to preclude its original intended use or application.

Specifically, the firm failed to take action appropriate to the effects, or potential effects, of the nonconformity" when nonconforming product has been delivered.

The firm distributed at least 51 of (b) (4) catheters documented in NCMR-00123 (created October 1, 2025) with (b) (4) to (b) (4) customers between May 14, 2025 and January 8, 2026.

The firm's Design FMEA (DOC-1498 Rev A, dated May 3, 2024, (b) (4) identifies insufficient SNR as a (b) (4) with risk control measure requiring (b) (4)

The firm failed to assess whether distributed units met design requirements or evaluate the risk to patients. On February 23, 2026, the firm stated: "There was no assessment of shipped product" and "There was no Field Action Decision."

NCMR-00123 remains in "Proposed" status with no disposition decision as of February 20, 2026.

For example:

- (b) (4) units shipped to (b) (4) customers (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jenny L Chisem, Investigator	X Jenny L Chisem Investigator Signed By: JENNY L. CHISEM -S Date Signed: 02-27-2026 14:19:44	2/27/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	2/17/2026-2/27/2026* FEI NUMBER 3016171942

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen E Ryan, President

FIRM NAME	STREET ADDRESS
PROVISIO MEDICAL INC	10815 Rancho Bernardo Rd Ste 110
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92127-2187	Manufacturer

☐ (b) (4) units shipped to (b) (4)
☐ (b) (4) unit shipped to (b) (4)

OBSERVATION 2
Design and development changes were not adequately reviewed, verified, validated, and approved before implementation.

Specifically, the firm implemented design changes to (b) (4) Catheter (b) (4) Software Requirements" before verification was complete and without evaluating the effect on product already delivered or risk management. (b) (4) is part of the firm's validated design, as evidenced by its inclusion in Phase 3, 4, and 5 Design History File checklists, with Design Transfer completed May 3, 2024 (Rev B).

1. Implementation before verification:
a. DCR (b) (4) (released May 27, 2025) for Rev C states (b) (4) (future tense). Verification was completed June 9, 2025 (b) (4) , (b) (4) after implementation. Changes included: (b) (4)
b. DCR (b) (4) (released July 30, 2025) for Rev D states (b) (4) (future tense). No validation report for Rev D was provided. Changes included: (b) (4)
(b) (4)
c. DCR (b) (4) (released September 19, 2025) for Rev E marks all process impacts (b) (4) Verification was completed September 24, 2025 (b) (4) after implementation. Changes included: (b) (4) (b) (4)
The firm's SOP-0004 Section 6.5 requires verification (b) (4) release and states DCRs (b) (4) (b) (4) (past tense). The use of future tense in DCRs and validation dates after DCR release demonstrate implementation before

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	2/17/2026-2/27/2026* FEI NUMBER 3016171942

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Stephen E Ryan, President	
FIRM NAME PROVISIO MEDICAL INC	STREET ADDRESS 10815 Rancho Bernardo Rd Ste 110
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92127-2187	TYPE ESTABLISHMENT INSPECTED Manufacturer

verification.

2. No evaluation of product already delivered:

None of the DCRs document evaluation of effect on product already delivered, as required by ISO 13485:2016 Clause 7.3.9 and SOP-0004 Section 6.4. Catheters tested under Rev B, C, and D criteria (May 2024 - September 2025) were not evaluated for impact of changed acceptance criteria.

3. No evaluation of risk management:

All DCRs mark "Risk Analyses Affected: No." DOC-0063 "Risk and Hazard Analysis" Rev R (dated October 5, 2025) contains zero hazards related to (b) (4) software, attenuation mechanism, or modified acceptance criteria, despite being updated (b) (4) revisions were released. Search of DOC-0063 Rev R for (b) (4) "attenuation," and "acceptance criteria" yielded zero results. This violates ISO 13485:2016 Clause 7.3.9 requirement to evaluate effect on risk management and SOP-0004 Section 6.4 requirement to analyze whether risk management file is impacted.

In response to a draft observation, the firm stated: (b) (4)
(b) (4)

In response to questions about the CPI change, the firm stated: (b) (4)
(b) (4)
(b) (4) This statement confirms the changes affect the Catheter (b) (4) Software (test equipment). However, the firm validated this test equipment as part of Design Validation (Phase 4 DHF, May 1, 2024). Per 21 CFR 820.30(d), design outputs include information for production and service provision. The Catheter (b) (4) Software provides production specifications (acceptance criteria) determining which catheters are released. Changes to production specifications constitute design changes requiring verification per 21 CFR 820.30(i), regardless of whether they affect test equipment or the medical device. The regulation does not exempt test equipment from design change requirements.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jenny L Chisem, Investigator	X Jenny L Chisem Investigator Signed By: JENNY L. CHISEM -S Date Signed: 02-27-2026 14:19:44	2/27/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	2/17/2026-2/27/2026* FEI NUMBER 3016171942

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Stephen E Ryan, President	
FIRM NAME PROVISIO MEDICAL INC	STREET ADDRESS 10815 Rancho Bernardo Rd Ste 110
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92127-2187	TYPE ESTABLISHMENT INSPECTED Manufacturer

OBSERVATION 3

Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence.

Corrective actions were not adequately taken to eliminate the cause of nonconformities to prevent recurrence, and the firm failed to assess the impact of specification changes on distributed product. Specifically:

1. The firm initiated CAPA-00016 on January 27, 2025, to address catheter failures with Signal-to-Noise Ratio (SNR) values (b) (4) affecting (b) (4) catheters (NCMR-00069). The firm closed CAPA-00016 on August 15, 2025, after reviewing (b) (4) work orders from March-May 2025 showing (b) (4) (b) (4) failure rate.
NCMR-00122, created September 29, 2025, documents (b) (4) pulse echo failures from May-September 2025, including (b) (4) failures from lot (b) (4) on September 29, 2025. The firm did not initiate a new CAPA or reopen CAPA-00016. Per ISO 13485:2016 Clause 8.5.2(f), the firm shall review the effectiveness of corrective action taken.
2. CAPA-00017 has remained in investigation status for 7 months (initiated July 18, 2025, status as of February 18, 2026) addressing (b) (4) nonconforming catheters (NCMR-00085) that failed pulse echo testing. The investigation and corrective actions have not been completed.
3. The firm did not initiate CAPAs for the following NCMRs documenting pulse echo test failures:
   - [redacted]CMR-00102 (created July 10, 2025): (b) (4) units
   - [redacted]CMR-00122 (created September 29, 2025): (b) (4) units
   - [redacted]CMR-00123 (created October 1, 2025): (b) (4) units

The NCMR records do not document evaluation of whether corrective action was needed. Per ISO 13485:2016 Clause 8.5.2(a), the firm shall review nonconformities and evaluate the need for action to eliminate causes of nonconformities.
4. On September 19, 2025, the firm increased the SNR acceptance criterion from (b) (4) via DCR (b) (4) . On October 1, 2025, the firm created NCMR-00123 documenting (b) (4) catheters from lots manufactured September 2024 through May 2025 that did not meet the new (b) (4) criterion.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jenny L Chisem, Investigator	X Jenny L Chisem Investigator Signed By: JENNY L. CHISEM -S Date Signed: 02-27-2026 14:19:44	2/27/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	2/17/2026-2/27/2026*
	FEI NUMBER 3016171942

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Stephen E Ryan, President	
FIRM NAME PROVISIO MEDICAL INC	STREET ADDRESS 10815 Rancho Bernardo Rd Ste 110
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92127-2187	TYPE ESTABLISHMENT INSPECTED Manufacturer

Distribution records show (b) (4) units from NCMR-00123 lots were distributed to customers between May 14, 2025, and January 8, 2026. The firm's NCMR-00123 record states: (b) (4) (b) (4) and (b) (4)

The firm did not document assessment of distributed product or field action decision.

For example:

- August 15, 2025: CAPA-00016 closed
- September 19, 2025: (b) (4)
- September 29, 2025: NCMR-00122 created (b) (4) failures)
- October 1, 2025: NCMR-00123 created (b) (4) units (b) (4) units distributed)
- February 18, 2026: CAPA-00017 remains in investigation (7+ months)
- No CAPA initiated for NCMR-00102, NCMR-00122, or NCMR-00123
- No assessment documented for (b) (4) distributed units from NCMR-00123 lots

***DATES OF INSPECTION**

2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/20/2026(Fri), 2/23/2026(Mon), 2/24/2026(Tue), 2/27/2026(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jenny L Chisem, Investigator	X Jenny L Chisem Investigator Signed By: JENNY L. CHISEM -S Date Signed: 02-27-2026 14:19:44	2/27/2026

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	2/17/2026-2/27/2026*
	FEI NUMBER 3016171942

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen E Ryan, President

FIRM NAME	STREET ADDRESS
PROVISIO MEDICAL INC	10815 Rancho Bernardo Rd Ste 110
CITY, STATE, ZIP CODE, COUNTRY San Diego, CA 92127-2187	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jenny L Chisem, Investigator X Jenny L Chisem Investigator Signed By: JENNY L. CHISEM -S Date Signed: 02-27-2026 14:19:44	2/27/2026

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."