DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	7/20/2026-7/22/2026 FEI NUMBER 2938071

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Allen R. Howes, President

FIRM NAME	STREET ADDRESS
Transamerican Technologies International	220 Porter Dr Ste 120
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Ramon, CA 94583-9206	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

A risk-based approach to the control of the appropriate processes needed for the quality management system has not been applied.

Specifically,

Your firm procedure Corrective and Preventive Action, QMP 0117, Revision 021126, effective date 2/11/2026, lacks risk-based assessment criteria and does not define a requirement to document an assessment of actual or potential risk for nonconforming product, nor does it require linking the product risk assessment to the firm's risk management documentation (e.g., Hazard Analysis). A review of your firm's Quality Preventive/Correction Action, Form 0018, Control number 106, dated 10/3/2022, documents that (b) (4) handpieces were shipped with the uncorrected part numbers for the product numbers (b) (4) A review of CAPA number 106 revealed that the firm did not conduct an assessment of actual or potential risk for product against the firm's risk management files (e.g., Hazard Analysis). When requested to provide the documentation, the firm was unable to provide it.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kevin T Le, Inspector X Kevin T Le Inspector Signed By: 2003985283 Date Signed: 07-22-2026 10:50:06	7/22/2026

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Design and development verification plans did not include methods, acceptance criteria and statistical techniques with rationale for sample size.

Specifically,

Your firm's Design Control Procedure, ACCU-Beam, ACCU-Surg, QMP 00120, Revision G, Effective Date 4/11/2022, Section 5.2.5, "Design and Development Verification," states that "verification shall be recorded on Form (b) (4) for methods, acceptance criteria, and as appropriate, statistical techniques with rationale for sample size." A review of the Design Output Review, Form (b) (4) dated 3/18/2013, documents the product design verification as "to be verified by (b) (4) after delivery of drawings with design specifications." Additionally, the Production Model Design Review, Form (b) (4) dated 10/14/2023, documents that "confirmed design output meets design input requirements 12/5/2013; released (b) (4) drawings as Rev A 12/6/2013." However, these forms contain no documented evidence that design verification activities were conducted. Specifically, no verification protocols, test reports, test results, or acceptance criteria are referenced, attached, or otherwise identified within the product design verification records to substantiate these claims. When asked, your firm was unable to provide objective evidence of design verification activities associated with the Fiber Optic Handpiece.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: 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."