DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	3/16/2026-3/19/2026
	FEI NUMBER 3003640911

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael J. Christie, Director of Operations

FIRM NAME	STREET ADDRESS
Viant San Antonio, Inc.	7027 Fairgrounds Pkwy
CITY, STATE, ZIP CODE, COUNTRY San Antonio, TX 78238-4544	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 WE OBSERVED:

OBSERVATION 1

In product realization planning your firm did not adequately determine, as appropriate, required activities specific to the product together with criteria for product acceptance.

Specifically, your firm has failed to adequately define required activities for Class II medical device tubing, intended for use in arthroscopy procedures, to ensure the realization process and resulting product meets requirements.

During a review of your firm's pFMEA for (b)(4) Tubesets, SAT-P-1169, Rev. 02, effective 06/03/2025, it was observed that your firm has identified multiple process failures which could result in the potential harm of a patient. However, the control implementations within the pFMEA are not adequately defined or conducted to indicate the reduction of risk throughout the production process.

Additionally, during a review of your firm's complaint records since 2024, it was observed that your firm has received 6 complaints for leaking of the tubing and 5 complaints for hair present in the tubing. However, the hazards and control implementations within the pFMEA are not adequately defined per the applicable process regarding the leaking or presence of hair in the tubing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Katherine M Thames, Investigator Richard T Riggie, Investigator	X Katherine M Thames Investigator Signed By: KATHERINE M. THAMES -S Date Signed: 03-19-2026 10:57:36	3/19/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	3/16/2026-3/19/2026
	FEI NUMBER 3003640911

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael J. Christie, Director of Operations

FIRM NAME	STREET ADDRESS
Viant San Antonio, Inc.	7027 Fairgrounds Pkwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Antonio, TX 78238-4544	Manufacturer

X Richard T Riggie
Investigator
Signed By: Richard T. Riggie -S
Date Signed: 03-19-2026 10:58:19

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Katherine M Thames, Investigator
Richard T Riggie, Investigator

X Katherine M Thames
Investigator
Signed By: KATHERINE M. THAMES -S
Date Signed: 03-19-2026 10:57:36

DATE ISSUED
3/19/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	3/16/2026-3/19/2026
	FEI NUMBER 3003640911

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael J. Christie, Director of Operations

FIRM NAME	STREET ADDRESS
Viant San Antonio, Inc.	7027 Fairgrounds Pkwy
CITY, STATE, ZIP CODE, COUNTRY San Antonio, TX 78238-4544	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Katherine M Thames, Investigator Richard T Riggie, Investigator X Katherine M Thames Investigator Signed By: KATHERINE M. THAMES -S Date Signed: 03-19-2026 10:57:36	3/19/2026

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."