DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	6/4/2026-6/11/2026* FEI NUMBER 3010197287

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kevin M. Murrock, Senior Director of Quality & Regulatory

FIRM NAME	STREET ADDRESS
Surgical Theater Inc	23645 Mercantile Rd Ste M
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Beachwood, OH 44122-5936	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

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

Specifically, post-market data, including complaints, does not appear to be consistently incorporated into updates to the Risk Management File. Sections 6.5 and 6.6 of your "Complaint Handling" procedure QSP4-01, Rev. J, dated 6/3/2026, require that risk evaluations be performed as part of complaint investigations and that results be documented directly in the complaint record. However, this practice has not been maintained since the transition to the current software-based complaint management system in January 2026.

Additionally, section 6.15.7 of your "Risk Management" procedure, QSP3-10, Rev. C, dated 9/29/2023, mentions collecting and reviewing production and post-production information; however, the procedure does not clearly describe the mechanism or process by which post-market data feeds back into the risk management file.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Laureen M Geniusz, Investigator X Laureen M Geniusz Investigator Signed By: LAUREEN M. GENIUSZ -S Date Signed: 06-11-2026 13:26:58	6/11/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	6/4/2026-6/11/2026*
	FEI NUMBER 3010197287

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kevin M. Murrock, Senior Director of Quality & Regulatory

FIRM NAME	STREET ADDRESS
Surgical Theater Inc	23645 Mercantile Rd Ste M
CITY, STATE, ZIP CODE, COUNTRY Beachwood, OH 44122-5936	TYPE ESTABLISHMENT INSPECTED medical device manufacturer

The document control procedure does not adequately define controls needed to review and approve documents for adequacy before use.

Specifically, your "Document and Change Control" procedure #QSP2-02, Rev H, dated 6/3/2026, does not ensure that training required due to documentation changes is completed and documented prior to implementation of the change. Specifically, the procedure refers to a training matrix to identify affected personnel but does not define a mechanism to verify training completion as part of the change control process.

OBSERVATION 3

Records of the results of the design and development reviews and any necessary actions were not adequately maintained or include identification of the design under review, the participants involved, and the date of the review.

Design reviews conducted for the SpineAR 2.0.0 release were not adequately documented. Specifically, "Design Plan," rev. 2, dated 10/15/2025, Task (b) (4) states to conduct a (b) (4) design review; however, no documentation exists that this review was conducted, including records of participants, date, action items, or associated due dates. Additionally, "Design Controls" procedure QSP3-01, rev. K, dated 6/3/2026, does not establish documentation requirements for design reviews.

***DATES OF INSPECTION**

6/04/2026(Thu), 6/05/2026(Fri), 6/08/2026(Mon), 6/09/2026(Tue), 6/10/2026(Wed), 6/11/2026(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Laureen M Geniusz, Investigator X Laureen M Geniusz Investigator Signed By: LAUREEN M. GENIUSZ -S Date Signed: 06-11-2026 13:26:58	6/11/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	6/4/2026-6/11/2026* FEI NUMBER 3010197287

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kevin M. Murrock, Senior Director of Quality & Regulatory	
FIRM NAME Surgical Theater Inc	STREET ADDRESS 23645 Mercantile Rd Ste M
CITY, STATE, ZIP CODE, COUNTRY Beachwood, OH 44122-5936	TYPE ESTABLISHMENT INSPECTED medical device manufacturer

Annotations to Observations

Observation 1: Promised to correct within 60 Days

Observation 2: Promised to correct within 90 Days

Observation 3: Promised to correct within 60 Days

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Laureen M Geniusz, Investigator X Laureen M Geniusz Investigator Signed By: LAUREEN M. GENIUSZ -S Date Signed: 06-11-2026 13:26:58	6/11/2026

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."