DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	3/18/2026-3/24/2026* FEI NUMBER 3003687489

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

James D. Murray, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Surgical Direct, Inc.	811 Harley Strickland Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orange City, FL 32763-7985	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

One or more processes for risk management in product realization have not been documented.

Specifically, your firm does not have risk management files for devices sold by Surgical Direct.

As a manufacturer, your firm is responsible for risk management throughout product realization.

OBSERVATION 2

Complaint handling records were not adequately maintained.

Specifically, complaint records are missing or incomplete.

For example, Complaint/RMA Numbers:

1. SDC34770999 dated 10/22/24
    a. Main form incomplete, Section 6 missing completion and signature
2. SDJ34770575 dated 6/14/24

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brandon P Thompson, Investigator	X Brandon P Thompson Investigator Signed By: Brandon P. Thompson -S Date Signed: 03-24-2026 16:44:56	3/24/2026

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a.Nonconformance Complaint Report Form 14.3 missing

3.SDJ34770089 dated 2/20/2024

a.No records maintained

OBSERVATION 3

Records of servicing activities carried out by your firm were not maintained.

Specifically,

Your firm performs repair and servicing operations on medical devices manufactured by Surgical Direct.

Servicing activities include sharpening, parts replacement, cleaning, and media blasting.

Your firm does not maintain records of servicing activities after repairs are completed.

OBSERVATION 4

Procedures for management review have not been adequately documented.

Specifically, your firm has not conducted management reviews.

OBSERVATION 5

Records of quality management system software validation activities were not maintained.

Specifically, your firm uses software to document and handle complaints, CAPA, and other QMS activities. This system was implemented mid-January 2026 but validation records are not maintained or

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documented.

***DATES OF INSPECTION**

3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/24/2026(Tue)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Brandon P Thompson, Investigator

X Brandon P Thompson
Investigator
Signed By: Brandon P. Thompson -S
Date Signed: 03-24-2026 16:44:56

DATE ISSUED

3/24/2026

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."