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	3/2/2026-3/5/2026
	FEI NUMBER 3027058844

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John Fulkerson, COO

FIRM NAME	STREET ADDRESS
Reflow Medical	20532 Crescent Bay Dr Ste 102
CITY, STATE, ZIP CODE, COUNTRY Lake Forest, CA 92630-8846	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.

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

Preventive action procedures describing the requirements for verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device and reviewing the effectiveness of the preventive action taken have not been documented.

Specifically, your firm's procedure, Corrective and Preventive Action SOP-0029 Rev. J Eff: 8/27/2025, does not require a Verification of Effectiveness for corrective or preventive actions, allowing QA to evaluate if one is required.

For example, your firm opened CAPA-000001 on 7/26/2024, a preventive action to review the quality management system. Your firm implemented corrective actions which include the implementation of an electronic quality management system to track and monitor nonconformances. Your firm closed the CAPA on 6/10/25 without an effectiveness check, justifying that one is not required as the preventive actions have been completed and QMS will continue to be tracked and trended.

OBSERVATION 2

Criteria for the evaluation and selection of suppliers were not based on the effect of the purchased product on the quality of the device and proportionate to the risk associated with the medical device.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kevin N Tran, Investigator X Kevin N Tran Investigator Signed By: 2002406436 Date Signed: 03-05-2026 13:54:44	3/5/2026

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Specifically, your firm's procedure, Supplier Quality SOP-0014 Rev. U Eff: 1/12/2026, describes the supplier risk level as driven by supplier risk, defining Level (b) (4) suppliers as one that provide goods that have a significant impact upon safety or effectiveness of finished device and a Level (b) (4) supplier as supplying components that can be adequately defined via specification. This risk level is based on the risk severity of your components, with Level II suppliers having components categorized with a severity category of (b) (4) and Level (b) (4) with a Severity category of (b) (4) Level (b) (4) firms are required to have a quality agreement with you firm and are evaluated every (b) (4) months; Level (b) (4) firms do not require a quality agreement and require evaluation every (b) (4) months.

Firm A provides a (b) (4) (P/N (b) (4), which allows the catheter to traverse through the vasculature, for your Class II Spur Peripheral Retrievable Stent System, intended to increase luminal diameter and restore flow in patients with de novo or restenotic lesions in the infrapopliteal arteries. Your firm's Approved Supplier List identifies Firm A as a Level (b) (4) supplier, even though your risk documentation, RSK-0013 Temporary Spur Stent, Component FMEA Rev. E Effective: 7/26/24, in index 1.5 (b) (4) (P/N (b) (4) identifies the component as a severity category of (b) (4) According to your procedure, with a severity category of (b) (4) Firm A is a Level (b) (4) supplier, one who supplies goods that have a significant impact upon safety or effectiveness of finished device. Your firm does not have a quality agreement with Firm A, as required for Level (b) (4) suppliers according to your procedure.

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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."