DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	3/24/2025-3/26/2025
	FEI NUMBER 3020707080

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stefan O. Wirth, President

FIRM NAME	STREET ADDRESS
FUJIFILM MEDWORK GMBH	Medworkring 1
CITY, STATE, ZIP CODE, COUNTRY Hochstadt Aisch, Bavaria, 91315 Germany	TYPE ESTABLISHMENT INSPECTED Manufacturing

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

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, your firm failed to report an adverse event to the FDA within 30 days.

A. During a review of complaint reports, Complaint #FP 5179, was initiated in response to a customer complaint in which parts of the "frog" biopsy valve were found inside a patient during a procedure. The incident occurred on [redacted] Germany. Evaluation of the complaint using your firm's Reportability Assessment form marks that no reporting to a notified body was deemed necessary despite proven causality between the device and the event. Your firm has distributed the same device in the United States since 2021, however, this event was not reported to the FDA by your firm.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Katlin N Stubbs, Investigator	X Katlin N Stubbs Investigator Signed By: Katlin N. Stubbs -S Date Signed: 03-26-2025 09:15:21	3/26/2025

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Katlin N Stubbs, Investigator	X Katlin N Stubbs Investigator Signed By: Katlin N. Stubbs -S Date Signed: 03-26-2025 09:15:21	3/26/2025

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."