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	5/13/2026-5/20/2026* FEI NUMBER 3001236129

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michelle P. Fritch , Director of Quality

FIRM NAME	STREET ADDRESS
Klarity Medical Products LLC	600 Industrial Pkwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Heath, OH 43056-1528	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

Procedures for validation of processes were not adequately documented.

Specifically, your firm utilizes the (b) (4) to (b) (4) the seams of the (b) (4) devices including the (b) (4) component assembly. The (b) (4) process is critical to the functioning of the (b) (4) device; however, you have not validated this manufacturing process to ensure you are consistently producing product that meets your acceptance criteria, in accordance with your Process/Process Validation [procedure], QMS 161, v1.0, 02-DEC-2022.

OBSERVATION 2

Records of the results of monitoring of supplier capability or performance were not maintained.

Specifically, according to your firm's Supplier Selection, Monitoring, and Control [procedure], QMS 210, v4.0, 28-OCT-2022:

Evaluation criteria for a Tier 1 Supplier focus on their capability to operate as an extension of Klarity's quality management system. This type of Supplier must maintain the outsourced process in conformity

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Javonica F Penn, Investigator X Javonica F Penn Investigator Signed By: JAVONICA F. PENN - S Date Signed: 05-20-2026 13:53:15	5/20/2026

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with applicable regulatory requirements. An audit of the Supplier by or on behalf of Klarity is required as part of the evaluation of this Supplier type. Audits may be conducted remotely when onsite audits are not feasible or when supplier risk is sufficiently low (e.g., based on historical performance or other methods of monitoring/control). In such cases, a documented rationale is required.

This is not routinely done. According to your firm's Director of Quality, you have not completed an audit of an identified Tier 1 Supplier of Class II medical devices and components, including the Klarity (b) (4) intended for (b) (4) of patients undergoing (b) (4) .

OBSERVATION 3

Reworked product was not adequately verified to ensure it meets applicable acceptance criteria and regulatory requirements.

Specifically, according to your firm's Control of Nonconforming Product [procedure], QMS 350, v3.0, 08-DEC-2022:

Rework must be performed according to a procedure that takes into account the potential adverse effect of rework on the product and must also include verification that reworked products meet applicable acceptance criteria and regulatory requirements. Any rework plan or procedure utilized must include the same review and approval as the original procedure.

This is not routinely done. For example:

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In response to customer complaint #QC2550084, dated 11/4/2025, a complainant informed you that one Klarity (b) (4), item # (b) (4), lot number (b) (4), had a broken (b) (4). You repaired the (b) (4), documented as Rework #30, dated 12/1/2025, when the (b) (4) was returned; however, you completed a " (b) (4) " in order to expedite the return to the customer. This is not consistent with what is described in your (b) (4) Testing and Test Log [procedure], (b) (4)-0701, v9.0, 25-NOV-2025, which requires a (b) (4) test prior to release.

OBSERVATION 4

Records of design and development changes and necessary actions associated with design and development changes were not maintained.

Specifically, according to your firm's Design and Development Control [procedure], QMS 410, v2.0, 25-MAY-2022:

Design changes, including changes to approved intended use, user needs, design inputs, and design outputs, including any associated acceptance criteria, shall be controlled and documented on QMS 410-13.

This is not routinely done.

- ☐ A review of the Class II Klarity (b) (4) Instructions for Use (IFU) revealed that revision update v2.0 included *additional cleaning instructions and referenced a* (b) (4) .

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☐A review of the Class II Klarity (b) (4) Instructions for Use (IFU), version 5.0, revision history indicated an *updated time to leave the* (b) (4) *on the* (b) (4) *in step* (b) (4)

You have no record of managing the mentioned changes to design inputs in accordance with your procedures.

***DATES OF INSPECTION**

5/13/2026(Wed), 5/14/2026(Thu), 5/15/2026(Fri), 5/19/2026(Tue), 5/20/2026(Wed)

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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

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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."