DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	3/30/2026-4/1/2026
	FEI NUMBER 1419823

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Conor J. O Malley , CEO

FIRM NAME	STREET ADDRESS
Oak Ridge Products, LLC	4612 Century Ct
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mchenry, IL 60050-7018	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

Records of design and development changes, the review of design and development changes and necessary actions associated with design and development changes were not adequately maintained.

Specifically, your firm failed to document, verify, and validate a design change from the first 510(k) submission (K130281) to the most recent (K161180), which includes additional sizes of the sharp containers and a change in the sharp container lid. Your firm's procedure, Design and Development (EP-730, Rev. E,03/27/2026 & Rev. D, 12/05/2012), requires all design changes to be initiated with a design change form and verified and validated before implementation. Your firm manufactures and is the specification developer of the Class II Slide Lid Sharp Containers (K161180, MMK), which are intended for use as single-use, disposable, non-sterile containers for safe disposal of hazardous sharps in healthcare settings. Your firm has distributed (b) (4) units since 2022.

OBSERVATION 2

Corrective action procedures defining the requirements for verifying that the corrective 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 corrective action taken have not been adequately documented.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shuana H Xiong, Investigator X Shuana H Xiong Investigator Signed By: Shuana H. Xiong -S Date Signed: 04-01-2026 15:06:30	4/1/2026

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Specifically, your firm failed to adequately verify that corrective actions do not adversely affect the ability to meet applicable regulatory requirements or safety and performance specifications and failed to document the results of the verification of effectiveness. Your firm's procedure, Corrective Action (QP-852, Rev. G, 03/26/2026, Rev. F, 01/17/2023 & Rev. E, 11/20/2012), requires verification of the actions and an indication of whether the action was effective. However, your firm failed to document the process for verifying the effectiveness of actions; eight corrective action records were reviewed and none had results documented for verification of effectiveness. Your firm manufactures and is the specification developer of the Class II Slide Lid Sharp Containers (K161180, MMK), which are intended for use as single-use, disposable, non-sterile containers for safe disposal of hazardous sharps in healthcare settings. Your firm has distributed (b) (4) units since 2022.

OBSERVATION 3

Procedures to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product were not adequately documented.

Specifically, your firm failed to document the identification, segregation, evaluation, and disposition of nonconforming product. Your procedure, Control of Nonconforming Product (QP-830, Rev. C, 01/07/2023), requires nonconforming products to be identified, segregated, labeled, evaluated, and dispositioned. However, your firm failed to document any steps described in your nonconforming product process. Your firm manufactures and is the specification developer of the Class II Slide Lid Sharp Containers (K161180, MMK), which are intended for use as single-use, disposable, non-sterile containers for safe disposal of hazardous sharps in healthcare settings. Your firm has distributed

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(b) (4) units since 2022.

OBSERVATION 4

Procedures for timely complaint handling have not been adequately documented.

Specifically, your firm failed to require documentation, evaluation, and investigation, if needed, of all received complaints. Your firm's procedure, Customer Related Processes (SP-720, Rev. E,03/27/2026 & Rev. D,01/18/2023), requires all complaints to be logged into the customer feedback log and categorized as minor or major; however, it does not require additional documentation, evaluation, or investigation of minor complaints. Your firm manufactures and is the specification developer of the Class II Slide Lid Sharp Containers (K161180, MMK), which are intended for use as single-use, disposable, non-sterile containers for safe disposal of hazardous sharps in healthcare settings. Your firm has distributed (b) (4) units since 2022.

OBSERVATION 5

Top management did not adequately review the quality management system at documented planned intervals to ensure its continued suitability, adequacy, and effectiveness.

Specifically, your firm failed to adequately perform and document management review meetings at the planned intervals. Your firm's procedure, Management Responsibility (AP-500, Rev. I,03/27/2026 & Rev. H, 01/17/2023), requires management review meetings to occur at a minimum of (b) (4) However, your firm did not perform management review meetings for years (b) (4) Your firm

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OBSERVATION 6

Internal audits have not been adequately conducted at planned intervals to determine whether the QMS conforms to planned and documented arrangements and applicable requirements and is effectively implemented and maintained.

Specifically, your firm failed to adequately conduct internal audits at planned intervals. Your firm's procedure, Internal Audits (QP-822, Rev. D, 01/15/2023), requires each area of the quality management system to be audited at a minimum of (b) (4) However, your firm failed to conduct internal audits for years (b) (4) Your firm manufactures and is the specification developer of the Class II Slide Lid Sharp Containers (K161180, MMK), which are intended to be used as single-use, disposable, non-sterile containers for healthcare purposes for safe disposal of hazardous sharps. Your firm has distributed (b) (4) units since 2022.

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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

Observation 6: Promised to correct

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X Shuana H Xiong
Investigator
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Date Signed: 04-01-2026
15:06:30

DATE ISSUED
4/1/2026

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."