DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	2/11/2026-2/23/2026* FEI NUMBER 3008493151

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Morgan E. Evans, Board Chair

FIRM NAME	STREET ADDRESS
SurgiSmoke Solutions	2300 Myrtle Ave Ste 200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Paul, MN 55114-1948	Specification developer and complaint file establishment

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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Design and development validation was not adequately completed prior to release for use of the product to the customer.

Specifically,

Your firm's previous top management documented in memo NC25-1, dated 02/25/2025, that your (b) (4) sterilized smoke capture device failed three-year shelf-life accelerated aging testing, caused by sterile wrap unsuitable for use with the (b) (4) sterilization, and by folding of the sterile barrier pouch:

- 8 of (b) (4) tested units exhibited holes in the sterile barrier pouch.
- 58 of (b) (4) tested units showed apparent deterioration of the sterile wrap into powder and disrupted fragments around the smoke capture device within the sterile barrier pouch.

Your design risk assessment, RMF_SSS_0003 Rev A, documents that packaging barrier insufficient to keep your smoke capture device sterile during its shelf-life, and particulate in the sterile field during surgery, are hazards that can result in serious severity systemic adverse reactions requiring professional medical intervention.

You shipped to customers for use your smoke capture devices from (b) (4) lots produced and packaged with the same materials, manufacturing, and sterilization processes as the production units that failed the accelerated aging testing, lots (b) (4). You received

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Albert L Nguyen, Investigator X Albert L Nguyen Investigator Signed By: Albert L. Nguyen -S Date Signed: 02-23-2026 15:01:42	2/23/2026

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two complaints that alleged your smoke capture devices from lot (b) (4) may have caused or contributed to infection or systemic adverse reaction requiring professional medical intervention, complaints 2025-001 and 2025-002.

Additionally, you distributed to customers for use your smoke capture devices labeled with a three-year shelf-life expiration date from lots (b) (4) (b) (4) without adequately documented validation to this shelf-life specification.

OBSERVATION 2

Planned and documented arrangements were not satisfactorily completed prior to product release or service delivery.

Specifically,

Your sterility assurance procedure SOP-0030 Rev A effective 04/17/2025 and Rev B effective 02/08/2026 requires (b) (4) audits to be performed every (b) (4) days to maintain sterilization validation for your commercially distributed products, however, you did not perform and document these (b) (4) audits for your smoke capture devices manufactured in (b) (4) of 2025. Furthermore, you shipped to customers for use your smoke capture devices from (b) (4) lots that were manufactured in (b) (4) of 2025, lots (b) (4)

OBSERVATION 3

Corrective action procedures defining the requirements for planning and documenting action needed and implementing such action and reviewing the effectiveness of corrective action taken have not been adequately documented.

Specifically,

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You did not adequately document corrective actions for NC25-1 and CAPA-00003:

- Your firm's previous top management documented in NC25-1 the packaging material and method corrective actions and preventive actions that were planned and initiated to address the failed accelerated aging validation testing for your smoke capture devices. However, you did not document verification that these actions were implemented and effective.
- You documented in CAPA-00003 the corrective actions and preventive actions that you planned and initiated to prevent recurrence of your failure to perform (b) (4) audits in (b) (4) of 2025. However, these actions did not address the smoke capture devices produced in (b) (4) of 2025 that were shipped to customers for use.

OBSERVATION 4

Top management did not adequately ensure that the integrity of the quality management system was maintained when changes to the quality management system were planned and implemented.

Specifically,

In April 2025, your firm's top management assumed responsibility for maintaining the integrity of the quality management system of your smoke capture device from your firm's previous top management, however, your quality plans implemented between April 2025 and February 2026 were not adequate to ensure that the failed and incomplete three-year shelf-life accelerated aging validation and associated corrective actions and preventive actions planned, initiated, and documented in NC25-1 by your firm's previous top management would be identified, handled, completed, and documented appropriately in a timely manner.

***DATES OF INSPECTION**

2/11/2026(Wed), 2/12/2026(Thu), 2/17/2026(Tue), 2/18/2026(Wed), 2/23/2026(Mon)

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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."