DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	10/30/2025-11/19/2025* FEI NUMBER 3010351679

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ryan J Peterson, Vice President of Operations

FIRM NAME	STREET ADDRESS
Blephex, LLC	500 Wilson Pike Cir Ste 103
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Brentwood, TN 37027-5252	Spec Developer/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

Complaint files are not adequately maintained.

Specifically,

Not all documented complaints have been reviewed and/or evaluated to determine whether an investigation is necessary and your firm is not documenting the reasons as to why an investigation was not initiated, as required by your Complaint Handling procedure (Rev 01), in Section 6.12. For example,

A. I reviewed 177 complaints, received (b) (4) about your powered eyelid cleaning sponge. None of the complaints contained documentation an investigation was performed, or a justification as to why no investigation was conducted.

B. Your firm opens complaints, but does not record when the complaints are closed, which is required per your firm's Complaint Handling procedure (Rev 01), Section 6.17. Therefore, whether complaints are being processed in a timely manner cannot be determined. Complaints are required to be processed in a timely manner. None of the 177 complaint records reviewed for the powered eyelid cleaning sponge contained a close date.

C. Complaints are not being evaluated to determine if the complaint should be reported to FDA. None of the 177 complaint records reviewed for the powered eyelid cleaning sponge were evaluated for MDR reporting. Examples include:

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE		DATE ISSUED
Nikki S Bryant, Investigator	X Nikki S Bryant Investigator Signed By: Nikki S. Bryant -S Date Signed: 11-19-2025 13:31:59	11/19/2025

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1. Complaint dated 9/9/2024 (Serial Number (b) (4)) alleged the handpiece of the class I powered eyelid cleaning sponge, "blew up." This complaint was not evaluated for reportability.

2. Complaint dated 9/2/14/2025 (Serial Number (b) (4)) alleged the handpiece of the class I powered eyelid cleaning sponge, "blew up." This complaint was not evaluated for reportability.

3. Complaint dated 1/21/2025 (Serial Number (b) (4) alleged that the handpiece of your firm's "began smoking." This event was not evaluated to determine if the event was reportable.

OBSERVATION 2

Corrective and preventive action activities and/or results have not been documented.

Specifically,

Your firm failed to document corrective actions taken when you found an issue with some of your Class I powered eyelid cleaning sponge in the field. Your firm was made aware of two medical devices (the Blephexes) that "blew up." Your firm made changes to the power plugs of the devices manufactured for the (b) (4) from a Type G plug to the USB plug.

You failed to take adequately corrective actions to address Class I powered eyelid cleaning sponge that "blew up." Specifically, you did not investigate the root cause. Your firm made changes to the power plugs of the devices manufactured for the (b) (4) from a Type G plug to the USB plug. However, you did not document the changes or verify and/or validate the action was effective and did not adversely affect the finished device.

OBSERVATION 3

Procedures for design control have not been established.

Specifically,

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Your firm manufactures and sales a medical device, the OptiVize, which is intended to deliver electric current to eyelid structures, including the lash follicle and meibomian glands, to vaporize biofilm. However, your VP of Operations confirmed you do not have Design Control procedures or a Design History File for the OpitVize medical device.

OBSERVATION 4

The type and extent of control to be exercised over the product and services was not clearly defined.

Specifically,

Your VP of Operations explained that your firm sold a BlephEx "Starter" kit which included a BlephEx handpiece, an anatomical eyelid model, tips, pamphlets, and a bottle of BlephEx Lid Cleanser. However, when I asked your VP of Operations for a copy of your firm's Service Quality Agreement with the manufacturer of the Cleanser, he stated, "[We have] no quality agreement with them." Control of the product and who holds the responsibility for products and services should be defined.

OBSERVATION 5

Procedures for device history records have not been established.

Specifically,

Procedures for device history records have not been established.

OBSERVATION 6

Procedures for training and identifying training needs have not been established.

Specifically,

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Procedures for training and identifying training needs have not been established.

OBSERVATION 7

Procedures for quality audits have not been established.

Specifically,

Procedures for quality audits have not been established.

*DATES OF INSPECTION

10/30/2025(Thu), 10/31/2025(Fri), 11/06/2025(Thu), 11/19/2025(Wed)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Under consideration

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

Observation 7: 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."