DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	10/27/2025-11/6/2025* FEI NUMBER 3013397886

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kostiantyn Suichmez, President

FIRM NAME	STREET ADDRESS
Advance-Esthetic LLC	4101 Ravenswood Rd Ste 110
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Lauderdale, FL 33312-5371	Initial Importer/ Distributor

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 corrective and preventive action have not been adequately established.

Specifically, your firm failed to implement your procedure "CORRECTIVE AND PREVENTIVE ACTION," Document ID 10.0, Revision 1, Dated 29 Aug 2023. Your firm has not adequately initiated, implemented, and verified the effectiveness of corrective and preventive actions as an integral part of your quality system. For instance:

1. Your firm did not initiate corrective actions to address issues identified during the previous FDA inspection, including:
    a. CAPA Obs-00324 was initiated on 10/28/2025 by your firm to address the deficient annual report submission process. However, the previous inspection had already identified this deficiency, and your firm did not initiate and implement preventive actions at the time to ensure timely submission of annual reports for laser products and prevent recurrence of the nonconformance. This deficiency was observed during the current inspection for the required annual reports that required submission in 2024 and 2025.
    b. The previous inspection identified that your firm had no standardized procedures to conduct management reviews and internal quality audits. However, your firm did not initiate a corrective and preventive action to ensure these procedures were established to

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	Monica C Burgos Garcia, Investigator	X Monica C Burgos Garcia Investigator Signed By: Monica C. Burgos-garcia -S Date Signed: 11-06-2025 13:27:04	11/6/2025

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define oversight mechanisms for continuous improvement and quality system effectiveness.

2. Your firm also failed to adequately implement corrective actions for calibration of testing equipment, for example:
   a. CAPA Obs-00924 was initiated by your firm on 02/12/2024 to address a lack of a procedure to ensure equipment is routinely calibrated. However, corrections implemented by your firm did not include the establishment of calibration procedures for testing equipment and instruments to prevent recurrence of identified deficiencies.

3. In addition, your firm failed to adequately verify the effectiveness of the corrections and corrective actions and documentation of corrections taken to fix distributed units.
   a. Your firm initiated CAPA Obs-00124 on 2/8/2024 for the Zemits Quidion diode laser due to non-adherence to the key-actuated master control performance standard. However, no records related to the quantity of units impacted by the correction, where the units had been shipped, the number of corrected units, and which customers were contacted to notify the correction were maintained by your firm.

OBSERVATION 2

Not all complaints have been adequately reviewed and evaluated to determine whether an investigation is necessary.

Specifically, a medical device report (MDR) submitted by a user was provided to you by the Agency. The user reported burns that were caused by your Zemits Quidion laser. However, your firm did not evaluate this report to determine the need for an investigation.

OBSERVATION 3

You did not notify the Secretary, in accordance with 21 CFR 1003.20, of an electronic product which failed to comply with an applicable Federal standard which you imported.

Specifically, your firm did not notify the FDA after initiating the corrections of an electronic product that was

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identified as failing to comply with applicable performance standards. On February 8, 2024, your firm opened CAPA Obs-00124 because a key-actuated master control was not incorporated in the Zemits Quidion diode laser therapy system (Class II). The corrections listed in the CAPA included "Rework of sold devices," and the effectiveness confirmation indicated that "Service teams reworked previously sold units by replacing the corresponding control parts to ensure full compliance across all distributed products." Your firm indicated that approximately (b) (4) units were distributed without the key-actuated master control. However, your firm was unable to provide records with specific details regarding these corrections.

OBSERVATION 4

You did not submit an annual report for products requiring one.

Specifically, your firm failed to timely submit annual reports for radiation-emitting electronic products. The annual reports for Class IV laser systems that you imported and distributed were due on September 1, 2024 (covering the period July 1, 2023, through June 30, 2024) and September 1, 2025 (covering the period July 1, 2024, through June 30, 2025). These reports were submitted late on October 20, 2025.

This is a repeated observation from the previous inspection.

OBSERVATION 5

Purchasing data that clearly describe or reference specified requirements for purchased or otherwise received product and services have not been adequately established.

Specifically, your firm has not established and maintained quality requirements as part of your purchasing data. These requirements should include responsibilities for adverse event reporting to the Agency and, where possible, agreements with provisions requiring suppliers to notify you of changes in their products. Your firm imports and distributes medical devices classified as Class II, including Class IV diode lasers, radio frequency devices, and other electronic products.

OBSERVATION 6

The manufacturer did not provide or cause to be provided in all catalogs, specification sheets and descriptive brochures pertaining to each laser product, a legible reproduction of the warning and the

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information required for positions 1, 2, and 3 of the applicable logotype required b to be affixed to the product.

Specifically, your firm failed to include required warning reproductions in marketing materials for Class IV laser products. Your Class IV laser systems, which are also classified as Class II medical devices, have required warnings affixed to the products per applicable performance standards. However, your firm's marketing brochures, product catalogs, and sales sheets provided to customers do not include reproductions of these required warnings as mandated by regulation.

For example, during the inspection, I reviewed marketing presentations for the Zemits Quidion diode laser system, Zemits DuoCratus, and Zemits YAGenix, as well as the Zemits Laser Product catalog, and observed that the required warning statements affixed to the laser products were not reproduced in these customer-facing materials.

***DATES OF INSPECTION**

10/27/2025(Mon), 10/28/2025(Tue), 10/29/2025(Wed), 10/30/2025(Thu), 10/31/2025(Fri), 11/04/2025(Tue), 11/06/2025(Thu)

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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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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."