DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	3/6/2026-3/31/2026* FEI NUMBER 3013986441

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Igor Trofimov, Managing Member

FIRM NAME	STREET ADDRESS
IVIMEA LLC	251 Old Pennington Lawrenceville Rd.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pennington, NJ 08543	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 to provide evidence of conformity to requirements and the effective operation of the quality management system have not been maintained.

Specifically,

A. There are no production, inspection, test, and acceptance records for the Eclipse 980 devices to show they were produced according to the procedures and met specifications.

B. There are no records of the acceptance of components used to produce the Eclipse 980 devices. The QP-743 Verifying Purchased Product R01.docx procedure, Section 4.2, Receiving Inspection, states the received items are checked against the approved chemicals list and the supplier order confirmation information. It also lists the items to be checked.

C. There are no records of the repair of the Eclipse 980 devices returned for repair.

OBSERVATION 2

Measuring equipment was not calibrated at specified intervals or prior to use.

Specifically, the power meter used to test the output of the Eclipse 980 was not calibrated. Procedure QP-760 Monitoring and Measurement Device Control R01.docx, Section 2, states all test and measurement equipment

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used in the inspection or evaluation of characteristics of products produced by IVIMEA is required to be identified, tracked, maintained and subject to periodic calibration.

OBSERVATION 3
Supplier performance in meeting requirements for the purchased product was not monitored.

Specifically, suppliers are not evaluated as required. The QP-741 Purchasing R01 procedure, Section 5.2, Supplier quality evaluations, states a periodic evaluation of the supplier's performance is performed and all suppliers shall be periodically re-evaluated at least (b) (4) per year. An example includes the supplier of the laser assemblies for the Eclipse 980 devices.

OBSERVATION 4
Design and development validation was not performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

Specifically, there was no record of the Mechanical Design Validation, Electrical Design Validation, Software design Validation, Functional/Operations Design Validation for the Eclipse 980 device. The QF-730 design and development checklist includes, under Design and Development Review and Validation, requirements for Mechanical Design Validation, Electrical Design Validation, Software Design Validation, Functional/Operations Design Validation.

OBSERVATION 5
Records of the results and conclusions of design and development validation and necessary actions were not adequately maintained.

Specifically, The QW-735-01 Design Validation Eclipse document has a table of identified issues, causes and proposed solutions for the Eclipse family of products. There are (b) (4) issues listed. There was no record of the changes being made to correct the issues. An example is the issue of (b) (4)
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(b) (4)

OBSERVATION 6

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

Specifically, management reviews were not conducted (b) (4) The QP-560 Management Review R01.docx procedure, Section 3.1, states management reviews will be performed (b) (4)

OBSERVATION 7

A risk-based approach to the control of the appropriate processes needed for the quality management system has not been adequately applied.

Specifically, the procedure: Production Risk Analysis does not show the processing steps or the steps to control risk. The Production Process Risk Analysis procedure, Section 4.1, states risks are selected for each of the elements as identified in the Process Flow Chart Quality Form, QF-711-01. Section 4.2 states these risks are entered into the (b) (4) Software Risk Management system for evaluation and analysis of the risk. The Process Flow Chart Quality Form, QF-711-01, includes steps such as receiving parts from vendor, rework, inspection, assembly, testing & calibration, ship to customer.

OBSERVATION 8

The release of labeling was not documented.

Specifically, there was no documentation of the labeling used on the Eclipse 980 devices to show that they were labeled in accordance with the medical device file.

OBSERVATION 9

Records of the review, evaluation, and investigation for any complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications were not maintained.

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Specifically, customer complaints are not documented. For example, the returned materials authorization list shows Eclipse 980 devices were returned for problems such as the laser power will not adjust down in any mode, smoke coming out of the handpiece, handpiece heats up, red laser blinking, button on the handpiece operates erratically, pressing the handpiece would not start the laser, button on the handpiece does not switch the laser on, no IR when the foot switch is pressed. The QP-723 Customer and Regulatory Communication R01 procedure, Section 4.4, Receiving Customer Complaints, states all customer complaints, whether written or verbal, are forwarded to President and are documented in (b) (4) Software Customer Feedback module, if the complaint (b) (4) (b) (4) (b) (4) .

OBSERVATION 10
Written MDR procedures have not been developed, maintained and implemented.

Specifically, your firm produces the Eclipse 980 devices and has no written medical device reporting procedures.

OBSERVATION 11
The correct unique device identifier (UDI) information regarding proprietary, trade, or brand name of the device as it appears on the label was not provided to the FDA via the Global Unique Device Identification Database (GUDID).

Specifically, the UDI number in the GUDID database for the Eclipse 980 device does not reference the Eclipse 980 name as the labeled name of the device.

OBSERVATION 12
Unique device identification (UDI) was not recorded for each medical device or batch of medical devices.

Specifically, the UDI numbers for the Eclipse 980 devices were not recorded for each device serial number produced.

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OBSERVATION 13
Each Class IV laser product does not have affixed a label bearing the DANGER logotype specified in the regulation.

Specifically, the Eclipse VLS and Eclipse 980 devices do not have an affixed label bearing the DANGER logotype.

OBSERVATION 14
A label bearing the wording: "Laser aperture". is not affixed to the medical laser product, in close proximity to the aperture through which was emitted accessible laser radiation in excess of the accessible emission limits of Class I.

Specifically, the Eclipse VLS and Eclipse 980 aperture labels did not have the wording "Laser aperture" affixed to the device.

OBSERVATION 15
You did not submit an (b) (4) report for products requiring one.

Specifically, there were no (b) (4) reports filed for the Eclipse VLS or Eclipse 980, which are class IV laser medical devices.

OBSERVATION 16
You did not submit a required product report prior to the introduction of the product into commerce.

Specifically, no product reports were filed for the Eclipse VLS and Eclipse 980, which are class IV laser products, prior to distribution.

OBSERVATION 17
Certification was not based upon a test, in accordance with the standard and a testing program in accordance with good manufacturing practices.

Specifically, the Eclipse 980 and Eclipse VLS devices are labeled as complying with 21CFR 1040.10 and

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1040.11. It does not certify that it complies with all applicable requirements in Title 21, Chapter I, Subchapter J. There is no test of each device for certification to the requirements and no testing program.

***DATES OF INSPECTION**

3/06/2026(Fri), 3/16/2026(Mon), 3/17/2026(Tue), 3/20/2026(Fri), 3/30/2026(Mon), 3/31/2026(Tue)

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Annotations to Observations

Observation 1: Promised to correct within 4 Weeks

Observation 2: Under consideration

Observation 3: Promised to correct within 4 Weeks

Observation 4: Promised to correct within 4 Weeks

Observation 5: Promised to correct within 4 Weeks

Observation 6: Promised to correct within 4 Weeks

Observation 7: Under consideration

Observation 8: Promised to correct within 4 Weeks

Observation 9: Promised to correct within 4 Weeks

Observation 10: Promised to correct within 4 Weeks

Observation 11: Promised to correct within 9 Weeks

Observation 12: Promised to correct within 4 Weeks

Observation 13: Under consideration

Observation 14: Under consideration

Observation 15: Promised to correct

Observation 16: Promised to correct

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Observation 17: Annotation Intentionally Left Blank

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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."