September 19, 2025

Ibramed Equipamentos Médicos
% Rodrigo Abreu
Regulatory Correspondent
United Regulatory & Logistics LLC
12343 NW 25th st
Coral Springs, Florida 33065

Re: K242859
Trade/Device Name: Vega
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 9, 2025
Received: September 9, 2025

Dear Rodrigo Abreu:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.09.19 19:47:12 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K242859

Device Name

VEGA

Indications for Use *(Describe)*

Vega Triple Wave Applicator (755nm/ 810nm/ 1064nm)
Indications for use of the Triple Wave Applicator, Includes:
The Super Hair Removal (SHR) mode is intended for the temporary reduction of hair.

Vega 810nm Applicator:
Indications for use of the 810nm Applicator, Includes:
The Hair Removal (HR) and Super Hair Removal (SHR) modes are intended for the permanent reduction of hair regrowth, defined as a stable and long-term reduction in the number of hairs that regrow, measured at 6, 9, and 12 months after completing a treatment regimen. It is suitable for use on all skin types (Fitzpatrick I-VI), including tanned skin, when using the HR and SHR mode.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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510(k) #: K242859

# 510(k) Summary

Prepared on: 2025-09-09

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
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## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | VEGA |
| Common Name | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| Classification Name | Powered Laser Surgical Instrument |
| Regulation Number | 878.4810 |
| Product Code(s) | GEX |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K222862 | SILKPRO Titanium Diode Laser System SILKPRO-S20S-TWC | GEX |
| K222064 | The Alma Soprano Titanium | GEX |

## Device Description Summary

21 CFR 807.92(a)(4)

VEGA is a high-power laser therapy device with electromagnetic emission in the infrared spectrum, designed for long-lasting hair removal on all skin types. Laser energy can be transferred to the treatment area via an 810nm or triple wave (755, 810, 1065nm) handpiece

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Vega Triple Wave Applicator (755nm/ 810nm/ 1064nm)

Indications for use of the Triple Wave Applicator, Includes:
The Super Hair Removal (SHR) mode is intended for the temporary reduction of hair.

Vega 810nm Applicator:
Indications for use of the 810nm Applicator, Includes:
The Hair Removal (HR) and Super Hair Removal (SHR) modes are intended for the permanent reduction of hair regrowth, defined as a stable and long-term reduction in the number of hairs that regrow, measured at 6, 9, and 12 months after completing a treatment regimen. It is suitable for use on all skin types (Fitzpatrick I-VI), including tanned skin, when using the HR and SHR mode.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for Use are the same for the subject and predicate device.

## Technological Comparison

21 CFR 807.92(a)(6)

Substantial Equivalence Discussion

The subject device (Vega Diode Laser Therapy, Triple Wave and 810 nm Applicators) is substantially equivalent to the predicate devices Alma Soprano Trio (K222064) and Lotuxs SILKPRO-S20S series (K222862) with respect to intended use, technological characteristics, and performance.

Intended Use / Indications for Use

Predicate (K222064 – Alma Soprano Trio): For the triple wavelength applicator (755m, 810 nm, and 1064nm):The SHR mode is indicated for temporary hair reduction; And for the 810nm applicator; HR mode is indicated for dermatologic procedures including benign vascular lesions.

Predicate (K222862 – Lotuxs SILKPRO-S20S): Indications include hair removal (HR mode) and SHR mode for permanent (755 nm applicator and 810nm applicator) on all Fitzpatrick skin types.; and for the triple wavelength applicator (755m, 810 nm, and 1064nm) temporary reduction of hair regrowth.

Subject Device: The Triple Wave handpiece (755/810/1064 nm) is indicated for temporary hair reduction using SHR mode. The dedicated 810 nm applicator is indicated for permanent reduction of hair regrowth, consistent with the indications of the predicate 810 nm modules.

Conclusion: The intended uses are the same or highly similar, with both subject and predicates covering SHR for temporary hair reduction and HR/SHR for longer-term hair reduction. No new indications are introduced.

Technological Characteristics

Laser Type & Wavelengths: The subject and predicates all use GaAlAs diode laser technology, delivering light at 755 nm, 810 nm, and 1064 nm wavelengths, combination or 810nm alone.

Delivery System & Handpieces: Both subject and predicate devices employ sapphire-tipped handpieces with similar spot sizes (1.5–4.0 $cm^2$ for predicates vs. 10×30 mm for subject device). Differences in spot dimensions are minor and do not raise safety or effectiveness concerns, since fluence and pulse parameters are equivalent.

Energy Density (Fluence):

Predicate devices operate in HR mode up to 120 $J/cm^2$ and SHR mode up to 20 $J/cm^2$.

Subject device Triple Wave SHR mode operates at 1–8 $J/cm^2$, within predicate ranges.

Subject device 810 nm applicator operates in SHR up to 21 $J/cm^2$ and HR up to 100 $J/cm^2$. This is consistent with predicate 810 nm applicators, which support similar values.
Conclusion: Minor differences in maximum SHR fluence (21 vs. 20 $J/cm^2$) are not clinically significant, as the subject device's range is encompassed within the clinical literature and predicate performance.

Pulse Width & Frequency: Subject device (1–200 ms, up to 10 Hz) matches predicate ranges (3.3–200 ms, up to 10 Hz). Differences expand rather than narrow the safe operating envelope and are supported by established diode laser safety profiles.

User Interface & Controls: All devices use color LCD touchscreens with footswitch/handpiece control. Equivalent.

Laser Classification: Class IV for all devices. Equivalent.

Target Population: For 810 nm applicator, device is indicated for all Fitzpatrick skin types (I–VI), including tanned skin. And, for triple wavelength applicator device is indicated for Fitzpatrick skin type (I-V), Equivalent.

Performance and Safety

The subject device employs the same fundamental principles of diode laser hair reduction as the predicates. The sapphire contact cooling system, pulse delivery algorithms (SHR, HR), and wavelength ranges are technologically identical. Literature cited in the predicate (Kirit et al., 2021) supports safety and effectiveness of SHR at fluences within the subject device's specifications. Bench validation and risk analysis confirm no new safety or effectiveness concerns are introduced by minor specification differences.

Conclusion

The Vega Diode Laser Therapy system (Triple Wave and 810 nm applicators) has the same intended use, similar technological characteristics, and equivalent performance as the predicate devices Alma Soprano Trio (K222064) and Lotuxs SILKPRO-S20S (K222862). Any differences (e.g., spot size variation, SHR fluence up to 21 J/cm$^2$) do not raise new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the identified predicates.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Conducting non-clinical tests on the subject device, as per international standard IEC 60601-2-22, ensures its reliability, safety, and performance. These tests evaluate functionality, environmental compatibility, safety features, and user interface, confirming the device's suitability for diverse non-clinical settings. Adhering to this standard demonstrate the device's acuracy, and regulatory compliance outside clinical environments, bolstering user confidence and minimizing risks.
As part of the substantial equivalence the predicate also demonstrate non-clinical test based on the IEC 60601-2-22.

In conclusion, the non-clinical testing conducted on the subject device in accordance with IEC 60601-2-22 confirms its reliability, safety, and performance. These evaluations validate the device's functionality, environmental compatibility, safety features, and user interface, ensuring its suitability for diverse non-clinical settings. Compliance with this standard demonstrates the device's accuracy and regulatory adherence, enhancing user confidence while minimizing risks. Furthermore, as part of the substantial equivalence assessment, the predicate device has also undergone non-clinical testing based on IEC 60601-2-22, reinforcing the subject device's comparability and compliance with industry standards.