April 1, 2025

AdvaLight APS
Amogh Kothare
Chief Scientific Officer
Industriparken 22A
Bellerup Hovedstaden, DK DK-2750
Denmark

Re: K250189
Trade/Device Name: AdvaTx
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: January 22, 2025
Received: January 22, 2025

Dear Amogh Kothare:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.04.01 15:01:47 -04'00'

for Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K250189

Device Name
AdvaTx

Indications for Use *(Describe)*
The ADVATx at 589 nm is indicated for use for dermatologic treatment of benign cutaneous vascular lesions including but not limited to: treatment of wrinkles, periocular wrinkles, periorbital wrinkles, facial and leg telangiectasia, rosacea. cherry ańgiomas, port wine stains, hemangiomas and venous lakes, angioma, spider angioma, Poikiloderma of Civatte, inflammatory acne vulgaris, verrucae/ warts, scars, striae, psoriasis and the treatment of benign pigmented lesions.

The ADV ATx at 1319 nm is indicated for treatment of fine lines and wrinkles. Treatment of atrophic acne scars. Treatment of mild and moderate inflammatory acne vulgaris.

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.

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510(k) Summary for AdvaTx K250189

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

I. Submitter Information [21 CFR 807.92(a) (1)]

Owner Name	AdvaLight APS
Address	Industriparken 22A Bellerup Denmark DK-2750
Contact Person	Amogh Kothare Chief Scientific Officer Adk@advalight.com 415-690-6796
Summary Preparation Date	February 20, 2024

II. Name of device [21 CFR 807.92 (a) (2)]

Device Name	Common Device Name(s) and Regulatory Class	Product Code(s)	Classification Panel	Regulation
AdvaTX	Laser Surgical Instrument for use in general and plastic surgery and in dermatology Class II	GEX	General & Plastic Surgery Panel	§ 21 CFR 878.4810

III. Intended use of device and Indications for Use [21 CFR 807.92(a) (5)]

The ADVATx at 589 nm is indicated for use for dermatologic treatment of benign cutaneous vascular lesions including but not limited to: treatment of wrinkles, periocular wrinkles, periorbital wrinkles, facial and leg telangiectasia, rosacea. cherry angiomas, port wine stains, hemangiomas and venous lakes, angioma, spider angioma, Poikiloderma of Civatte, inflammatory acne vulgaris, verrucae/ warts, scars, striae, psoriasis and the treatment of benign pigmented lesions.

The ADVATx at 1319 nm is indicated for treatment of fine lines and wrinkles. Treatment of atrophic acne scars. Treatment of mild and moderate inflammatory acne vulgaris.

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IV. Device Description [21 CFR 807.92(a) (4)]

The AdvaTx is non-ablative laser with two wavelengths: 1319nm and 589nm. There are multiple indications for use that are specific to each wavelength. The AdvaTx consists of a console, a handpiece that has a scanner and a distance guide. The laser is activated using a trigger that is located on the handpiece.

The AdvaTx produces light pulses with a specific duration, intensity, and spectral distribution allowing for a controlled and confined energy delivery into tissue. Laser use in dermatology relies on the basis that certain targets for energy absorption (chromophores) are capable of absorbing energy from the specific light wavelength (absorptive band) without exclusively being targeted by their highest absorption peak. The working basis of the laser rests on the principle of selective photothermolysis, in which thermally mediated radiation damage is confined to chosen epidermal and/or dermal pigmented targets at the cellular or tissue structural levels

V. Summary of technological characteristics of the device compared to the predicate [21 CFR 807.92(a)(6)]

The subject device and the predicate device share the same technical characteristics with one exception. The fluence for the 1319nm laser is increased to 60J/cm2. This is the same fluence as the reference device.

This submission has one predicate device and two reference devices as stated in the table below.

Predicate K Number	Predicate / Reference Name
K132976	AdvaTX
K033176	Cynocure TriStar Aesthetic Workstation
K043251	Candela VBeam

Indication for Use and Technical Characteristics Comparison Table

	AdvaTx (Subject Device)	AdvaTx K132976 (Predicate Device)	VBeam (Reference Device)	TriStar (Reference Device)	Comparison
	The ADVATx at 589 nm is indicated for use for dermatologic treatment of benign cutaneous vascular lesions including but not limited to: treatment of wrinkles, periocular wrinkles, periorbital wrinkles, facial and leg telangiectasia, rosacea. cherry angiomas, port wine stains, hemangiomas and venous lakes, angioma, spider angioma, Poikiloderma of Civatte, inflammatory acne vulgaris, verrucae/ warts, scars, striae, psoriasis and	The ADVATx at 589 nm is indicated for use for dermatologic treatment of benign cutaneous vascular lesions including but not limited to: treatment of wrinkles, periocular wrinkles, periorbital wrinkles, facial and leg telangiectasia, rosacea. cherry angiomas, port wine stains, hemangiomas and venous lakes, angioma, spider angioma, Poikiloderma of Civatte, inflammatory acne	The candela family of pulse dye laser systems is indicated for the following uses in: general surgery: photocoagulation of benign cutaneous vascular lesion and benign cutaneous lesions. Dermatology/plastic surgery: for treatment of benign cutaneous vascular lesion, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, poikiloderma of civatte, and benign cutaneous lesions, such as warts, scars, striae and psoriasis, and the treatment of wrinkles.	1064nm: the tristar laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, stiae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age sports), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucea, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and	Different as the subject device has the addition of the benign pigmented lesion indication which is subject to this 510K

	AdvaTx (Subject Device)	AdvaTx K132976 (Predicate Device)	VBeam K043251 (Reference Device)	TriStar K033176 (Reference Device)	Comparison
	Treatment of Benign Pigmented Lesions. The ADVATx at 1319nm is indicated for treatment of fine lines and wrinkles. Treatment of atrophic acne scars. Treatment of mild and moderate inflammatory acne vulgaris.	vulgaris, verrucae/ warts, scars, striae, psoriasis. The ADVATx at 1319nm is indicated for treatment of fine lines and wrinkles. Treatment of atrophic acne scars. Treatment of mild and moderate inflammatory acne vulgaris.	- Treatment of inflammatory acne vulgaris. - Gynecology: photocoagulation of benign cutaneous lesion and benign vascular lesion in gynecology. - Podiatry: treatment of benign cutaneous lesions, such as warts. New indication: treatment of benign epidermal pigmented lesion	plaques. the later is also indicated for the treatment of wrinkles such as but not limited to, periocular and perioral wrinkles. additionally, the laser is indicated for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment of pseudofolliculitis barbae (pfb). 1320nm: the tristar laser is indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles. It is also indicated for the treatment of fine lines and wrinkles.	

	AdvaTx (Subject Device)	AdvaTx K132976 (Predicate Device)	VBeam (Reference Device)	TriStar (Reference Device)	Comparison
				585nm: the tristar aesthetic workstation laser is indicated for benign vascular and vascular dependent lesions removal.	
Wavelength (nm)	589 1319	Same	(595, 532, 755)	1320	589 nm and 595 nm are considered substantially equivalent 1319 nm and 1320 nm are also considered substantially equivalent
Spot Size (mm)	1.0	Same	3-12	3-10	Subject device spot size is smaller than those of the predicate device and reference devices. This will not have any additional safety risks as compared to the predicates
Pulse Width (ms)	20-950 @ 589 20-200 @ 1319	20-950 @ 589 20-200 @ 1319	0.4 - 40 @595	0.5-40	
Fluence (J/cm^2)	Up to 100 @ 589 Up to 60 @ 1319	Up to 100 @ 589 Up to 40 @ 1319	Up to 13.5 @ 595	Up to 60 @ 1320	
Repetition Rate (Hz)	0.67 - 1.0	Same	Max 1.5	1-3	

	AdvaTx (Subject Device)	AdvaTx K132976 (Predicate Device)	VBeam (Reference Device)	TriStar (Reference Device)	Comparison
Power Supply	110-240 V, 50/60 Hz	Same	200-240 VAC	200/220 VAC/30A	
Dimensions HxWxD (cm)	135 x 50 x 62	Same	unknown	114 x 50 x 58.5	
Weight (kg)	63	Same	127	136	

VI. Performance Testing [21 CFR 807.92(b)(1)]

The following performance data was provided in support of the substantial equivalence determination:

IEC 60601-1 Edition 3.2 2020-08 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance.

IEC 60601-1-2:2014 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility

IEC 60601-2-22: 2012 Test for Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process

Software verification and validation testing was conducted and documentation provided as recommended by the FDA's "Guidance for the Content of Premarket Submissions Contained in Medical Devices.

VII. Clinical Data [21 CFR 807.92(b) (2)]

Based on the similarities in the safety and effectiveness profiles of the subject and the predicate, no clinical studies were deemed needed to support this submission.

VIII. Conclusions Safety and Effectiveness SE [21 CFR 807.92(b) (3)]

AdvaTx is as safe and effective as the predicate device. The proposed AdvaTx has the same intended use and indications, same technological characteristics, and same principle of operation as its predicate device. The addition of the higher fluence does not present any new concerns for safety or efficacy. Thus, AdvaTx is substantially equivalent to its predicate.