December 20, 2024

Vydence Medical
Antonio Olivatto
Executive Vice President, Global, Vydence Medical
Rua Aldo Germano Klein, 359. CEAT
Sao Carlos, SP 13573-470
Brazil

Re: K242534
Trade/Device Name: HandPICO Fractional Laser Handpiece Tip
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: August 1, 2024
Received: August 26, 2024

Dear Antonio Olivatto:

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: 2024.12.20 18:53:33 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242534

Device Name
handPICO® Fraction Laser Handpiece Tip

Indications for Use *(Describe)*

The handPICO® Fraction Laser Handpiece Tip, when used with the Etherea-MX and Zye lasers at 1064 nm in picosecond mode, is indicated for:

• Removal of tattoos on all skin types (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple.
• Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.
• Treatment of acne scars in Fitzpatrick Skin Types II-V.
• Treatment of wrinkles in Fitzpatrick Skin Types I-IV.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K242534

Preparation date: 12 December 2024

Submitter and Owner:

Vydence Medical

Rua Aldo Germano Klein, 359. CEAT

Sao Carlos, Brazil, 13573-470

Official Correspondent:

Jamie Owsiany, Director of Clinical Operations

Hoy and Associates Regulatory Consulting

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Submission Type: Traditional 510(k)

Proprietary Name: handPICO® Fractional Handpiece Tip

Device Classification Information:

Classification Name: Laser Surgical Instrument for Use in General and& Plastic Surgery and in Dermatology Regulation Number: 878.4810

Product Code: GEX

Device Class: II

Primary Predicate: K191842 Quanta Discovery Pico

Secondary Predicate: K191685 PicoWay Laser system with Resolve handpiece

Device Description:

This 510(k) adds the handPICO® Fractional Laser Handpiece Tip, which is specifically designed for the ETHEREA MX and ZYE® LASERs manufactured by Vydence Medical Inc. The handPICO Fractional Handpiece Tip is a fractional optical element micro lens array that attaches to the handPICO handpiece. The producing 280 microbeams/cm2 and a total of 100 microbeams spaced 600 µm apart.

Indications/Intended use:

The handPICO® Fractional Laser Handpiece Tip, when used with the Etherea-MX and Zye lasers at 1064 nm in picosecond mode, is indicated for:

• Removal of tattoos on all skin types (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple.

• Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.

• Treatment of acne scars in Fitzpatrick Skin Types II-V.

• Treatment of wrinkles in Fitzpatrick Skin Types I-IV.

Indications for Use Comparison:

Subject device	**Primary Predicate**	**Secondary Predicate**	**Comparison**
Vydence handPICO® Fractional Laser Handpiece Tip K242534	Discovery Pico (Quanta) K191842	PicoWay (Candela) K191685	
Removal of tattoos on all skin types (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple. Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV. Treatment of acne scars in Fitzpatrick Skin Types II-V. Treatment of wrinkles in Fitzpatrick Skin Types I-IV.	Removal of tattoos for all skin types (Fitzpatrick skin types I-VI) to treat the following tattoo colors: black, brown, green, blue and purple Benign pigmented lesions removal for Fitzpatrick skin types I-IV. With fractional handpiece, indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V. With fractional handpiece, indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV	Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple. Benign pigmented lesions removal for Fitzpatrick Skin Types I-IV. Treatment of acne scars in Fitzpatrick Skin Types II-V	The handPICO® Fractional Laser Handpiece Tip and the Discovery Pico and Candela PicoWay have the same indications for use.

	SUBJECT	PRIMARY PREDICATE	SECONDARY PREDICATE	Same/Different
MANUFACTURER	Vydence Medical	Quanta	Candela	N/A
DEVICE MODEL	HandPICO® Fractional Laser Handpiece Tip for the Vydence Laser Family	PicoWay laser system with the Resolve handpiece Discovery Pico	Picoway Laser System with the Resolve handpiece	N/A
510K	This submission	K191842	K191685	N/A
CLASSIFICATION	Class II	Class II	Class II	Same
LASER SOURCE	Q-Switched Nd:YAG	Q-Switched Nd:YAG	Q-Switched Nd:YAG	Same
WAVELENGTH	1064nm	1064nm	1064nm	Same
PULSE WIDTH	530 ps	450ps	450ps	Similar; see discussion below
REPETITION RATE (MAX)	Single pulse to 10Hz	Single pulse to 10 Hz	Up to10 Hz	Same
SPOT SIZE	6x6 mm	8mm DF and 9mm HC Fractional Round	6x6 mm	Similar
FLUENCE (MAX)	3.0 mJ/microbeam	5.73mJ/microbeam	2.9 mJ/microbeam	Different – see discussion below

Technological characteristics comparison:

The maximum fluence for the handPICO® fractional laser handpiece tip is 3.0 mJ/microbeam, for the primary predicate is 5.73 mJ/microbeam, and for the secondary predicate is 2.9 mJ/microbeam. The fluence of the handPICO® fractional laser handpiece tip is within the range of the primary predicate and reference predicate.

The beam diameter for the handPICO® fractional laser handpiece tip is 151 mm, for the Picoway is 150 mm and for the Quanta discovery is 200 mm. The beam diameter for the handPico is within the range of the primary and reference predicates. The microbeam spacing (600 mm) for the handPico is the same as Picoway.

The pulse duration of the handPico® fractional laser handpiece tip is 530 ps, the Picoway is 450 ps and the Quanta is 450 ps. This difference of 80 ps is considered to be acceptable.

Clinical Testing Summary:

A histological analysis was performed after treatment with the handPico® fractional laser handpiece tip. The purpose of the study was to assess histological changes after treatment at 1-, 2-, and 3 mJ at Day 0, Day 3, Day 7, Day 14, and Day 21 after treatment. Four participants were treated with the device at the stated timepoints prior to abdominoplasty.

No serious adverse events occurred and the observed histological changes resolved within three weeks of treatment.

Non Clinical Testing:

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

IEC 60601-1 Ed. 3.0 (2005) +AMD. 1 (2012) Medical electrical equipment – Part 1: General requirements for safety and essential performance

IEC 60601-1-2 Ed. 4.0 (2014) Medical electrical equipment – Part 1-2 General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC 60601-2-22:2007 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

ISO 14971 Medical Devices - Applications of Risk Management To Medical Devices

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.

Statement of Substantial Equivalence:

Vydence Medical has demonstrated that the handPICO Fractional handpiece has the same device classification, same intended use and basic technological characteristics as the predicate device.

Biocompatibility: Compliance to ISO-10993 Standard

An analysis of the biocompatibility of the materials of the Vydence laser family that have potential, or expected patient contact during use was conducted in accordance with and met the biocompatibility testing requirements per the flowchart included in FDA guidance document entitled "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" effective as of September 14th, 2016.

Materials with Potential of Patient Contact

The only components with patient contact are those located at the hand piece tips where the tip of the hand pieces (or the standoffs) are placed in direct contact with the patient skin to deliver laser/light energy during the treatment. These components are sapphire crystals, aluminum 6351, and acetal.

The following biocompatibility tests were performed:

- Cytotoxicity
- Sensitization
- Irritation reactivity

Software Verification and Validation Testing:

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

Conclusions Safety and Effectiveness:

The handPICO® Fractional Laser Handpiece Tip, when used with the handPICO handpiece and the Etherea MX and Zye Laser platforms, is as safe and effective as the predicate devices. The handPICO® has the same intended use and indications, similar technological characteristics, and same principle of operation as its predicate devices. Thus, the handPICO® Fractional Laser Handpiece Tip is substantially equivalent to its predicate.