



January 24, 2026

Vydenze Medical Industria E Commercio Ltda
% Connie Hoy
Consultant
Hoy & Associates Regulatory Consulting, LLC
1830 Bonnie Way
Sacramento, California 95825

Re: K252753

Trade/Device Name: Vydenze Family of Lasers

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, ONF, PDZ

Dated: August 23, 2025

Received: January 15, 2026

Dear Connie Hoy:

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: 2026.01.24

09:06:14 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252753

?

Please provide the device trade name(s).

?

Vydence Family of Lasers

Please provide your Indications for Use below.

?

IPL 390nm-510nm Filter

- The treatment of inflammatory acne (acne vulgaris);
- The treatment of leukoderma, including vitiligo (acquired leukoderma).

IPL 400nm-1200nm Filter

- The treatment of moderate inflammatory acne vulgaris;
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles);
- The treatment of benign cutaneous lesions including warts, scars and striae;
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, Poikiloderma of Civatte, leg veins and venous malformations.
- Use on all skin types (Fitzpatrick I-VI).

IPL 515-1200nm Filter

- The treatment of moderate inflammatory acne (acne vulgaris).
- The treatment of tattoos and benign pigmented epidermal and benign cutaneous lesions including warts, scars, striae, dyschromia, hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair growth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime.
- Use on all skin types (Fitzpatrick I-V).

IPL 540nm-1200nm Filter

- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles),
- Lentigines, nevi, and café-au-lait macules;
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The treatment of benign cutaneous lesions including warts, scars and striae.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair growth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime.
- Use on all skin types (Fitzpatrick I-VI).

IPL 540nm-1200nm Filter

- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles),
- lentigines, nevi, and cafe-au-lait macules;
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The treatment of benign cutaneous lesions including warts, scars and striae.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair growth is defined as the long-term , stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime.
- Use on all skin types (Fitzpatrick I-VI).

IPL 580nm-1200nm Filter

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles).
- The treatment of face and body benign vascular and benign pigmented lesions.
- The treatment of benign cutaneous lesions, including scars and striae.
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. . Permanent reduction in hair growth is defined as the long-term , stable reduction in the number of hairs regrowing when measured at 6,9 an 12 months after the completion of a treatment regime.
- Use on all skin types (Fitzpatrick I-VI).

IPL 640nm-1200nm Filter

- The treatment of tattoos;
- The treatment of mild to moderate inflammatory and pustular inflammatory acne vulgaris;
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and cafe-au-lait;
- The treatment of benign cutaneous lesions including warts, scars and striae;
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
- Removal of unwanted hair, for stable long term or permanent hair reduction (permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen).
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

IPL 695nm-1200nm Filter

- Removal of unwanted hair, for stable long term or permanent hair reduction (permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen).
- Use on all skin types (Fitzpatrick I-VI), including tanned skin

Intense IR Handpiece

Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature. It's also indicated for the treatment in the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in

local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

1064nm Long Pulse Handpiece

- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime
- Treatment of pseudofolliculitis barbae (PFB)
- Benign vascular lesions such as, but not limited to treatment of: Port wine stains; Hemangiomas; Warts; Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas
- Benign pigmented lesions such as, but not limited to: Lentigos (age spots); Solar lentigos (sun spots); Café-au-lait macules; Seborrheic keratoses; Nevi and nevus of Ota; Chloasma; verrucae, skin tags, keratoses, the removal of black, blue, or green tattoos (significant reduction in the intensity of black and/or blue/black tattoos), plaques
- Benign cutaneous lesions, such as, but not limited to warts, scars, striae and psoriasis
- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to: Periocular wrinkles, Perioral wrinkles
- Laser skin resurfacing procedures for the treatment of: Acne scars, wrinkles
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar;

1064nm Long Pulse Handpiece - Short Pulse Operation

- Intended for the coagulation and hemostasis of benign vascular lesions such as but not limited to, rosacea/ diffuse redness, poikiloderma of civatte, scar reduction (including hypertrophic and keloidscars), and warts.
- Is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.
- For use on all skin types (Fitzpatrick I-VI), including tanned skin.

1064nm Long Pulse Handpiece – Onychomycosis

- Podiatry (i.e. ablation, vaporization, incision, excision, and coagulation of soft tissue) including matrixectomy, radical nail excision, periungual and subungual warts, plantar warts, neuromas,
- Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Trichophyton mentagrophytes, and/or yeasts Candida albicans, etc.).

Acroma Handpiece

The 1064 nm wavelength is indicated for:

- Treatment of benign vascular lesions such as (but not limited to): port wine stains; hemangiomas; warts; superficial and deep telangiectasias (venulectasias); reticular veins (0.1-4.0 mm diameter) of the leg; rosacea; venous lakes; leg veins; spider veins; Poikiloderma of Civatte; angiomas;
- Benign cutaneous lesions, such as, but not limited to: warts; scars; striae; psoriasis;
- Benign pigmented lesions such as, but not limited to: lentigos (age spots); solar lentigos (sun spots); cafe-au-lait macules; seborrheic keratoses; nevi and Nevus of Ota; chloasma; verrucae; skin tags; keratoses; the removal of black, blue or green tattoos (significant reduction in the intensity of black and/or blue/black tattoos); plaques;

- Pigmented benign lesions to reduce lesions' size for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, including but not limited to: periocular wrinkles; perioral wrinkles;
- Laser skin resurfacing procedures for the treatment of acne scars; wrinkles,
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The 532 nm wavelength is indicated for:

- Incision, excision, ablation, vaporization of soft tissue;
- Tattoo removal: light blue, yellow, red; green;
- Benign vascular lesions: Hemangiomas (port wine stains/birthmarks, cavernous, cherry, spider, hemangiomas); angiomas (cherry, spider); telangiectasias; spider nevi;
- Benign pigmented lesions: cafe-au-lait macules; lentigines (senile and solar); freckles (ephelides); chloasma; nevi; nevus spillus; Nevus of Ota; Becker's Nevi;
- Other benign pigmented cutaneous lesions: verrucae; skin tags; keratoses; plaques

1540 GoSmooth Handpiece

- The 1540 Fractional Non-ablative Laser Handpiece is intended for use in the coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.

2940 DualMode Handpiece

Dermatology and Plastic Surgery:

- Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins;
- Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars); Debulking benign tumors; Debulking cysts; Superficial skin lesions; Diagnostic biopsies; Decubitus ulcers;
- Podiatry
- Treatment of warts, plantar verrucae, large mosaic verrucae
- Matrixectomy

2940 DualMode Fractional

- Skin Resurfacing

1340nm ProDeep Handpiece

- Non-ablative laser handpiece is intended for use in skin resurfacing

ProDeep 6mm collimated handpiece:

- Treatment of fine lines and wrinkles, Treatment of atrophic acne scars, Treatment of mild to moderate inflammatory acne vulgaris

755nm Fiber Delivered Handpiece

755nm Handpiece (Zye and One)

- Intended for the temporary and permanent hair reduction on all skin types (Fitzpatrick I-VI), including tanned skin. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime; epidermal lesions (benign pigmented lesions) such as solar melanosis, hyperpigmentation, melasma, and ephelides, wrinkles, treatment of benign cutaneous lesions with vascular components including port wine stains, hemangiomas, facial and bodily telangiectasia, erythematous rosacea, angiomas and spider angiomas, poikiloderma of Civatte and superficial venous malformations.

1064nm Fiber Delivered Handpiece (Zye and One)

- In long pulse mode, the ZYE YAG® applicator is designated for coagulation and hemostasis of vascular lesions and epidermal tissue, including the treatment of telangiectasia, superficial varicosities, angiomas and spider angiomas, hemangiomas, rosacea, and nevi. It is also designated for non-ablative treatment of facial wrinkles and for removal of unwanted hair, for stable long term or permanent hair reduction (permanent hair reduction is defined as the long-term, stable reduction in the number of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen); for the treatment of pseudofolliculitis barbae (PFB). Use on all skin types (Fitzpatrick I-VI), including tanned skin.
- In the DYNAMICS® mode, for temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *Trichophyton mentagrophytes*, and/or yeasts *Candida albicans*, etc.).
- In the INTENSE® mode is intended for non-invasive Laser assisted lipolysis;”

HandPICO Handpiece

532nm (pico-second):

- Removal of tattoos for Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange;
- Treatment of benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.

1064nm (pico-second):

- 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.

532nm (nano-second):

- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV
- Removal of lighter colored tattoo inks, including red and yellow inks, on Fitzpatrick skin types I-III

1064nm (nano-second):

- Treatment of benign pigmented lesions on Fitzpatrick skin types I-VI
- Removal of dark and multi-colored tattoos containing dark colored tattoo inks on Fitzpatrick skin types I-VI

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.

The Zye Ultra is indicated for:

755 nm:

Intended for the temporary and permanent hair reduction on all skin types (Fitzpatrick I-VI), including tanned skin. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime; epidermal lesions (benign pigmented lesions) such as solar melanosis, hyperpigmentation, melasma, and ephelides, wrinkles, treatment of benign cutaneous lesions with vascular components including port wine stains, hemangiomas, facial and bodily telangiectasia, erythematous rosacea, angiomas and spider angiomas poikiloderma of Civatte and superficial venous malformations.

1064nm

In long pulse mode, the ZYE YAG® applicator is designated for coagulation and hemostasis of vascular

lesions and epidermal tissue, including the treatment of telangiectasia, superficial varicosities, angiomas and spider angiomas, hemangiomas, rosacea, and nevi. It is also designated for non-ablative treatment of facial wrinkles and for removal of unwanted hair, for stable long term or permanent hair reduction (permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen); for the treatment of pseudofolliculitis barbae (PFB). Use on all skin types (Fitzpatrick I-VI), including tanned skin.

- In the DYNAMICS® mode, for temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Trichophyton mentagrophytes, and/or yeasts Candida albicans, etc.).
- In the INTENSE® mode is intended for non-invasive Laser assisted lipolysis;"

Please select the types of uses (select one or both, as applicable).	<input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D)	?
	<input type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)	

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Vydence Medical Industria E Comercio Ltda
Applicant Address	Rua Also Germano Klein, 359 CEP:13.573-470-Caixa Postal 772 Sal Carlos 13.573.470 Brazil
Applicant Contact Telephone	+5516981836891
Applicant Contact	Mr. Eduardo Gabriel
Applicant Contact Email	egabriel@vydence.com
Correspondent Name	Hoy & Associates Regulatory Consulting, LLC
Correspondent Address	1830 Bonnie Way Sacramento CA 95825 United States
Correspondent Contact Telephone	5309084903
Correspondent Contact	Ms. Connie Hoy
Correspondent Contact Email	conniehoy@hoyregulatory.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Vydence Family of Lasers
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, ONF, PDZ

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190007	Vydence Family of Lasers	GEX,PDZ, ON ₊
K242534	HandPico Fractional	GEX
K220041	HandPico	GEX

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Vydence Family of Lasers consists of five models of configurable platforms that include up to nine different handpieces. The Vydence Family has multiple modalities including IPL and IR handpieces. In addition, there is a variety of different wavelength laser handpieces including 1064nm, 532nm, 1540nm, 2940nm, 1340nm and 755nm. The Zye Ultra model has a feature that includes a blended mode which emits 755 nm Alex and 1064nm Nd:YAG laser energy sequentially

IPL 390nm-510nm Filter

- The treatment of inflammatory acne (acne vulgaris);
- The treatment of leukoderma, including vitiligo (acquired leukoderma).

IPL 400nm-1200nm Filter

- The treatment of moderate inflammatory acne vulgaris;
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles);
- The treatment of benign cutaneous lesions including warts, scars and striae;
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, Poikiloderma of Civatte, leg veins and venous malformations.
- Use on all skin types (Fitzpatrick I-VI).

IPL 515-1200nm Filter

- The treatment of moderate inflammatory acne (acne vulgaris).
- The treatment of tattoos and benign pigmented epidermal and benign cutaneous lesions including warts, scars, striae, dyschromia, hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair growth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime.
- Use on all skin types (Fitzpatrick I-V).

IPL 540nm-1200nm Filter

- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles),
- Lentigines, nevi, and café-au-lait macules;
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The treatment of benign cutaneous lesions including warts, scars and striae.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair growth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime.
- Use on all skin types (Fitzpatrick I-VI).

IPL 540nm-1200nm Filter

- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles),
- lentigines, nevi, and café-au-lait macules;
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The treatment of benign cutaneous lesions including warts, scars and striae.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair growth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime.
- Use on all skin types (Fitzpatrick I-VI).

IPL 580nm-1200nm Filter

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles).
- The treatment of face and body benign vascular and benign pigmented lesions.
- The treatment of benign cutaneous lesions, including scars and striae.
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair to effect stable long-term or permanent hair reduction. . Permanent reduction in hair growth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 an 12 months after the completion of a treatment regime.
- Use on all skin types (Fitzpatrick I-VI).

IPL 640nm-1200nm Filter

- The treatment of tattoos;
- The treatment of mild to moderate inflammatory and pustular inflammatory acne vulgaris;

- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and cafe-au-lait;
- The treatment of benign cutaneous lesions including warts, scars and striae;
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
- Removal of unwanted hair, for stable long term or permanent hair reduction (permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen).
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

IPL 695nm-1200nm Filter

- Removal of unwanted hair, for stable long term or permanent hair reduction (permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen).
- Use on all skin types (Fitzpatrick I-VI), including tanned skin

Intense IR Handpiece

Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature. It's also indicated for the treatment in the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

1064nm Long Pulse Handpiece

- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime
- Treatment of pseudofolliculitis barbae (PFB)
- Benign vascular lesions such as, but not limited to treatment of: Port wine stains; Hemangiomas; Warts; Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas
- Benign pigmented lesions such as, but not limited to: Lentigos (age spots); Solar lentigos (sun spots); Café-au-lait macules; Seborrheic keratoses; Nevi and nevus of Ota; Chloasma; verrucae, skin tags, keratoses, the removal of black, blue, or green tattoos (significant reduction in the intensity of black and/or blue/black tattoos), plaques
- Benign cutaneous lesions, such as, but not limited to warts, scars, striae and psoriasis
- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to: Periocular wrinkles, Perioral wrinkles
- Laser skin resurfacing procedures for the treatment of: Acne scars, wrinkles
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar;

1064nm Long Pulse Handpiece - Short Pulse Operation

- Intended for the coagulation and hemostasis of benign vascular lesions such as but not limited to, rosacea/ diffuse redness, poikiloderma of civatte, scar reduction (including hypertropic and keloidscars), and warts.
- Is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioralwrinkles.
- For use on all skin types (Fitzpatrick I-VI), including tanned skin.

1064nm Long Pulse Handpiece – Onychomycosis

- Podiatry (i.e. ablation, vaporization, incision, excision, and coagulation of soft tissue) including matrixectomy, radical nail excision, periungual and subungual warts, plantar warts, neuromas,
- Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Trichophyton mentagrophytes, and/or yeasts Candida albicans, etc.).

Acroma Handpiece

The 1064 nm wavelength is indicated for:

- Treatment of benign vascular lesions such as (but not limited to): port wine stains; hemangiomas; warts; superficial and deep telangiectasias (venulectasias); reticular veins (0.1-4.0 mm diameter) of the leg; rosacea; venous lakes; leg veins; spider veins; Poikiloderma of Civatte; angiomas;
- Benign cutaneous lesions, such as, but not limited to: warts; scars; striae; psoriasis;
- Benign pigmented lesions such as, but not limited to: lentigos (age spots); solar lentigos (sun spots); cafe-au-lait macules; seborrheic keratoses; nevi and Nevus of Ota; chloasma; verrucae; skin tags; keratoses; the removal of black, blue or green tattoos (significant

reduction in the intensity of black and/or blue/black tattoos); plaques;

- Pigmented benign lesions to reduce lesions' size for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, including but not limited to: periocular wrinkles; perioral wrinkles;
- Laser skin resurfacing procedures for the treatment of acne scars; wrinkles,
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The 532 nm wavelength is indicated for:

- Incision, excision, ablation, vaporization of soft tissue;
- Tattoo removal: light blue, yellow, red; green;
- Benign vascular lesions: Hemangiomas (port wine stains/birthmarks, cavernous, cherry, spider, hemangiomas); angiomas (cherry, spider); telangiectasias; spider nevi;
- Benign pigmented lesions: cafe-au-lait macules; lentigines (senile and solar); freckles (ephelides); chloasma; nevi; nevus spillus; Nevus of Ota; Becker's Nevi;
- Other benign pigmented cutaneous lesions: verrucae; skin tags; keratoses; plaques

1540 GoSmooth Handpiece

- The 1540 Fractional Non-ablative Laser Handpiece is intended for use in the coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.

2940 DualMode Handpiece

Dermatology and Plastic Surgery:

- Skin resurfacing; Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins;
- Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars); Debulking benign tumors; Debulking cysts; Superficial skin lesions; Diagnostic biopsies; Decubitus ulcers;

• Podiatry

• Treatment of warts, plantar verrucae, large mosaic verrucae

• Matrixectomy

2940 DualMode Fractional

- Skin Resurfacing

1340nm ProDeep Handpiece

- Non-ablative laser handpiece is intended for use in skin resurfacing

ProDeep 6mm collimated handpiece:

- Treatment of fine lines and wrinkles, Treatment of atrophic acne scars, Treatment of mild to moderate inflammatory acne vulgaris

755nm Fiber Delivered Handpiece

755nm Handpiece (Zye and One)

- Intended for the temporary and permanent hair reduction on all skin types (Fitzpatrick I-VI), including tanned skin. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime; epidermal lesions (benign pigmented lesions) such as solar melanosis, hyperpigmentation, melasma, and ephelides, wrinkles, treatment of benign cutaneous lesions with vascular components including port wine stains, hemangiomas, facial and bodily telangiectasia, erythematous rosacea, angiomas and spider angiomas, poikiloderma of Civatte and superficial venous malformations.

1064nm Fiber Delivered Handpiece (Zye and One)

- In long pulse mode, the ZYE YAG® applicator is designated for coagulation and hemostasis of vascular lesions and epidermal tissue, including the treatment of telangiectasia, superficial varicosities, angiomas and spider angiomas, hemangiomas, rosacea, and nevi. It is also designated for non-ablative treatment of facial wrinkles and for removal of unwanted hair, for stable long term or permanent hair reduction (permanent hair reduction is defined as the long-term, stable reduction in the number of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen); for the treatment of pseudofolliculitis barbae (PFB). Use on all skin types (Fitzpatrick I-VI), including tanned skin.
- In the DYNAMICS® mode, for temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Trichophyton mentagrophytes, and/or yeasts Candida albicans, etc.).
- In the INTENSE® mode is intended for non-invasive Laser assisted lipolysis;

HandPICO Handpiece

532nm (pico-second):

- Removal of tattoos for Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange;
- Treatment of benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.

1064nm (pico-second):

- 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.

532nm (nano-second):

- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV
- Removal of lighter colored tattoo inks, including red and yellow inks, on Fitzpatrick skin types I-III

1064nm (nano-second):

- Treatment of benign pigmented lesions on Fitzpatrick skin types I-VI
- Removal of dark and multi-colored tattoos containing dark colored tattoo inks on Fitzpatrick skin types I-VI

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.

The Zye Ultra is indicated for:

755 nm:

Intended for the temporary and permanent hair reduction on all skin types (Fitzpatrick I-VI), including tanned skin. Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime; epidermal lesions (benign pigmented lesions) such as solar melanosis, hyperpigmentation, melasma, and ephelides, wrinkles, treatment of benign cutaneous lesions with vascular components including port wine stains, hemangiomas, facial and bodily telangiectasia, erythematous rosacea, angiomas and spider angiomas poikiloderma of Civatte and superficial venous malformations.

1064nm

In long pulse mode, the ZYE YAG® applicator is designated for coagulation and hemostasis of vascular lesions and epidermal tissue, including the treatment of telangiectasia, superficial varicosities, angiomas and spider angiomas, hemangiomas, rosacea, and nevi. It is also designated for non-ablative treatment of facial wrinkles and for removal of unwanted hair, for stable long term or permanent hair reduction (permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen); for the treatment of pseudofolliculitis barbae (PFB). Use on all skin types (Fitzpatrick I-VI), including tanned skin.

- In the DYNAMICS® mode, for temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and Trichophyton mentagrophytes, and/or yeasts Candida albicans, etc.).
- In the INTENSE® mode is intended for non-invasive Laser assisted lipolysis;"

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The Indications for Use are the same as the predicate devices.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The technological characteristics are the same as the predicate devices with one exception. The Zye Ultra configuration has new software which is due to this model being a new configuration to the product family.

The Zye Ultra now has a feature that includes a blended mode which emits 755nm Alex and 1064nm Nd:YAG laser energy sequentially.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The Vyidence Family of Lasers that are the subject of this 510k pre-market notification underwent non-clinical testing including:

The following additional testing was performed to support substantial equivalence:

- Electrical safety and EMC testing per IEC 60601-1, IEC 60601-1-2, IEC 60601-1 and IEC 60601-2-22
- Software validation testing

There was no clinical testing performed to support substantial equivalence.

The Vydence Family of Lasers is the same or similar in design, intended use, principles of operation, and technological characteristics, compared to the predicate devices. The minor differences in the subject device to the predicate does not raise new types of questions with regards to safety and effectiveness. The testing provided in this 510k support that the device can be used safely and effectively for the proposed indications for use.

The Vydence Family of Lasers that are the subject of this 510K are considered to be substantially equivalent to the predicate devices.