October 26, 2021

Vydence Medical Industria E Comercio Ltda
℅ Kathy Maynor
Regulatory Consultant
Kathy Maynor
26 Rebecca Ct
Homosassa, Florida 34446

Re: K202998
Trade/Device Name: Vydence Zye and Vydence One
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, PDZ, ONF
Dated: September 30, 2020
Received: October 1, 2020

Dear Kathy Maynor:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Purva Pandya
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202998

Device Name

Vydence Zye and Vydence One

Indications for Use *(Describe)*

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 cafè-aulait 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 an 12 months after the completion of a treatment regime.
• Use on Fitzpatrick skin types I-V.

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 treament 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); Cafè-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 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

1340 ProDeep Handpiece
• fractional laser handpiece is intended for use in skin resurfacing
• collimated laser handpiece is intended for the treatment of fine lines and wrinkles; treatment of atrophic acne scars;

treatment of mild to moderate inflammatory acne vulgaris

755nm Fiber Delivered Handpiece (Zye and One)
755nm
• 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 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;

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)

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