



February 14, 2025

Wontech Co., Ltd.
Hyun Sik Yoon
Regulatory Affairs Team General Manager
64 Techno 8-ro, Yuseong-gu
Daejeon, 34028
Korea, South

Re: K241527

Trade/Device Name: Pastelle Pro

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: May 28, 2024

Received: May 30, 2024

Dear Hyun Sik Yoon:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TANISHA L.
HITHE -S

Digitally signed by TANISHA
L. HITHE -S
Date: 2025.02.14 15:47:11
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Tanisha Hithe, MS, MHS
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

510(k) Number (*if known*)
K241527

Device Name
Pastelle Pro

Indications for Use (*Describe*)

The Pastelle Pro system is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

1064nm in nanosecond mode, including microbeam handpieces:

- Tattoo removal: dark ink (black, blue, and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of melasma

1064nm in Genesis (long-pulse) mode:

- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 595 nm and 660 nm with optional dye handpieces):

- Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of Lentigines
- Treatment of Café-au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyperpigmentation
- Treatment of Becker's Nevi, Freckles, and Nevi spilus

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.

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510(k) Summary (K241527)

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

February 12, 2025

2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: WON TECH Co., Ltd.
- Address: 64 Techno 8-ro, Yuseong-gu, Daejeon, 34028,
Republic of Korea
- Contact Name: Hyun Sik Yoon
- Telephone No.: +82 42 934 6800
- Fax No.: +82 42 934 9491
- Email Address: regulatory@wtlaser.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Common name: Nd:YAG Laser System

Trade name: Pastelle Pro

Classification Description	21 CFR Section	Product Code
Laser surgical instrument for use in general and plastic surgery and in dermatology	878.4810	GEX

As stated in 21 CFR, part 878.4810, this generic type of devices has been classified as Class II.

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate device 1

- 510(k) Number: K213569
- Applicant: Lutronic

- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology, 21 CFR 878.4810, Class II
- Product Code: GEX
- Trade Name: HOLLYWOOD SPECTRA Laser System

Predicate device 2

- 510(k) Number: K161670
- Applicant: Bison Medical Co., Ltd.
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology, 21 CFR 878.4810, Class II
- Product Code: GEX
- Trade Name: Lucid Q-PTP

Predicate device 3

- 510(k) Number: K202503
- Applicant: Quanta System Spa
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology, 21 CFR 878.4810, Class II
- Product Code: GEX
- Trade Name: Chrome

5. Description of the Device [21 CFR 807.92(a)(4)]

The Pastelle Pro laser system consists of an Nd:YAG laser head, a power supply, a cooling system, a delivery system and other electrical components. The laser head contains two Nd:YAG laser medium, and two high-intensity xenon flash lamps enclosed together into the water cooling housing and two reflected mirrors fixed, in the special adjustable holders composed the laser cavity.

To provide energy to the flash lamp, high voltage power supply charges to a storage capacitor. Then, a trigger pulse applied to the flash lamps causes the capacitor to discharge through the flash lamps. The resulting flash excites the Nd:YAG laser rod, causing the emission of a pulse of laser energy.

The electro-optic modulator with a polarizer introduced into the cavity creates the picoseconds pulse irradiation pulses. The basic frequency of 1064 nm can be doubled by a KTP crystal, which can be inserted to a working area. The sealed top metal cover protects all optical components from dust and humidity and blocks the visible and invisible scattering light from the laser head.

The system delivers laser energy at a wavelength of 1064 nm, 532 nm, 595 nm and 660 nm. The output of the laser is delivered to the area of treatment through an Articulated Arm with a handpiece. A trigger (foot switch) controls the delivery of pulses. The user selects and sets the treatment parameters and other functions operated by software on the graphical user interface.

6. Statement of Intended Use [21 CFR 807.92(a)(5)]

The Pastelle Pro system is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

1064nm in nanosecond mode, including microbeam handpieces:

- Tattoo removal: dark ink (black, blue, and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of melasma

1064nm in Genesis (long-pulse) mode:

- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 595 nm and 660 nm with optional dye handpieces):

- Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of Lentigines
- Treatment of Café-au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyperpigmentation
- Treatment of Becker's Nevi, Freckles, and Nevi spilus

7. Summary of Technological Characteristics [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between the Pastelle Pro and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics.

	Proposed Device	Predicate Device #1	Predicate Device #2	Predicate Device #3	SE Decision
K Number	-	K213569	K161670	K202503	-
Manufacturer	WON TECH Co., Ltd.	Lutronic Corporation	Bison Medical Co., Ltd.	Quanta System Spa	-
Model	Pastelle Pro	HOLLYWOOD SPECTRA Laser System	Lucid Q-PTP	Chrome	-
Product Code	GEX	GEX	GEX	GEX	Same as predicate #1
Intended Use	<p>The Pastelle Pro system is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.</p> <p>1064nm in nanosecond mode, including microbeam handpieces:</p> <ul style="list-style-type: none"> - Tattoo removal: dark ink (black, blue, and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation - Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of melasma <p>1064nm in Genesis (long-pulse) mode:</p> <ul style="list-style-type: none"> - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris <p>532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 595 nm and 660 nm with optional dye handpieces):</p> <ul style="list-style-type: none"> - Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) 	<p>The HOLLYWOOD SPECTRA System is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatological and general surgical procedures for coagulation and hemostasis.</p> <p>1064nm in nanosecond mode, including microbeam handpieces:</p> <ul style="list-style-type: none"> - Tattoo removal: dark ink (black, blue, and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation - Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of melasma <p>1064nm in Spectra (long-pulse) mode:</p> <ul style="list-style-type: none"> - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris <p>532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):</p> <ul style="list-style-type: none"> - Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) - Removal of Epidermal Pigmented Lesions 	<p>The LUCID Q-PTP Nd:YAG Laser System is indicated for the incision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedure for coagulation and hemostasis</p> <p>532nm wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):</p> <ul style="list-style-type: none"> - Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) - Removal of Epidermal Pigmented Lesions, Minor Vascular Lesions Telangiectasias - Treatment of Lentigines, Café-au-Lait, Seborrheic Keratoses, Post Inflammatory Hyperpigmentation - Treatment of Becker's Nevi, Freckles, and Nevi spilus" <p>1064nm wavelength:</p> <ul style="list-style-type: none"> - Tattoo removal: dark ink (black, blue, and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation - Treatment of Common Nevi, Melasma - Skin resurfacing procedures for the treatment of acne scars and wrinkles 	<p>Chrome is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization and coagulation of body soft tissues in the medical specialties of dermatology, general, plastic and oral surgery as follows.</p> <p>Indications for use</p> <p>1064 & 532 nm (Q-Switched, nanosecond mode)</p> <p>Chrome is intended for treatment of benign vascular lesions, benign pigmented lesions, and for hair, tattoo removal and the incision, excision, ablation, vaporization of soft tissue for General dermatology such as, but not limited to treatment of:</p> <p>532 nm (Q-Switched, nanosecond mode), including microbeam handpieces:</p> <p>Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos Treatment of benign vascular lesions including, but not limited to: - port wine birthmarks - telangiectasias - spider angioma - Cherry angioma - Spider nevi</p> <p>Treatment of benign pigmented lesions including, but not limited to: - cafe-au-lait birthmarks - Ephalides, solar lentigines - senile lentigines - Becker's nevi - freckles - common nevi - nevus spilus - Ota Nevus</p> <p>Treatment of seborrheic keratosis</p> <p>Treatment of post inflammatory hyperpigmentation</p> <p>Skin resurfacing procedures for the treatment of acne scars and wrinkles.</p> <p>1064 nm (Q-Switched, nanosecond mode), including microbeam handpieces:</p> <p>Removal of dark ink (black, blue and brown) tattoos</p> <p>Removal of benign pigmented lesions including: - nevus of Ota - Café au lait spot - Ephalides, solar lentigo (lentigines) - Becker Nevus - Nevus spilus</p> <p>Treatment of common nevi Removal or lightening of</p>	Same as predicate #1

	<ul style="list-style-type: none"> - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of Lentigines - Treatment of Café-au-Lait - Treatment of Post Inflammatory Hyperpigmentation - Treatment of Becker's Nevi, Freckles, and Nevi spilus 	<ul style="list-style-type: none"> - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of Lentigines - Treatment of Café-au-Lait - Treatment of Seborrhic Keratoses - Treatment of Post Inflammatory Hyperpigmentation - Treatment of Becker's Nevi, Freckles, and Nevi spilus 		<p>unwanted hair Skin resurfacing procedures for the treatment of acne scars and wrinkles 1064 nm (pulsed)</p> <p>Dermatology/Plastic Surgery: 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, striae and psoriasis.</p> <p>The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrhic keratoses, nevi, chloasma, verrucae, skin tags, keratosis and plaques.</p> <p>The laser is also indicated for the treatment of wrinkles such as, but not limited to, periorcular and perioral wrinkles.</p> <p>The laser is also indicated for the treatment of facial wrinkles.</p> <p>Additionally, the laser is indicated for the treatment of pseudofolliculitis barbae (PFB) and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as 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.</p> <p>It is indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.</p> <p>The laser is also indicated for benign pigmented lesions to reduce lesion size, for patients with benign lesions that would potentially benefit from aggressive treatment, and for patients with benign lesions that have not responded to other laser treatments.</p> <p>It is indicated for use on all skin types (Fitzpatrick I-VI) including tanned skin, and the removal and permanent reduction of unwanted hair in Fitzpatrick I-VI, including suntanned skin types.</p> <p>IPL 590-1200nm; 625-1200nm; 650-1200nm Indicated for permanent hair removal. Permanent hair reduction 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</p> <p>IPL 550-1200nm; 570-1200nm Indicated for photocoagulation of dermatological benign vascular lesion (i.e. face telangiectasia), photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions.</p> <p>IPL 400-1200nm Indicated for inflammatory acne (mild to moderate acne vulgaris).</p> <p>Integrated Skin Cooler The intended use of the integrated cooling system in the laser hand piece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluencies for laser treatments such as hair removal and benign vascular lesion, and to reduce the potential side effects of laser treatments. Any other different use is considered incorrect.</p>	
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Principle/Method of Operation	<p>The Pastelle Pro laser system consists of an Nd:YAG laser head, a power supply, a cooling system, a delivery system and other electrical components. The laser head contains two Nd:YAG laser medium, and two high-intensity xenon flash lamps enclosed together into the water cooling housing and two reflected mirrors fixed in the special adjustable holders composed the laser cavity.</p>	<p>The HOLLYWOOD SPECTRA Laser System contains a Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) resonator which generates Q-switched and/or pulsed laser sources at the nominal wavelength of 1064 nm and 532 nm using KTP. The outputs of each laser generator and the aiming beam (655 nm) are delivered by articulated arm to a fixed (collimated), or focusing variable (zoom) spot handpiece, or a dual focused dots microbeam handpiece, or a 585nm/650nm dye laser converter handpiece. The dye handpieces convert the KTP 532 nm wavelength beam into a 585 nm or 650 nm wavelengths, correspondingly.</p>	<p>The LUCID Q-PTP Q-Switched Nd:YAG laser system produces a two pulsed beam, 1064nm Infrared and 532nm long pulse laser, and optional 2 dye handpieces are available that convert the 532nm wavelength to 585nm and 650nm, using difference handpiece able to control various treatment fluence</p>	<p>Chrome is a laser family that includes Q-Switched and/or Pulsed laser sources, emitting at 532 nm and 1064 nm (Nd:YAG laser). Chrome, through the special universal Twain connector, can be equipped with intense pulsed light handpieces (Twain IPL) emitting at the following wavelengths: 650-1200nm, 625-1200nm, 590-1200nm, 570-1200nm, 550-1200nm, 400-1200nm. It can also be connected to Er:YAG handpieces cleared under K173002.</p>	Same
Laser Material	Nd:YAG	Nd:YAG	Nd:YAG	Nd:YAG	Same as predicate #1

	Proposed Device	Predicate Device #1	Predicate Device #2	Predicate Device #3	SE Decision
Radiation diameter	<p>Zoom: 2mm ~ 10mm Collimation: 7mm MLA: 3mm ~ 8mm DOE: 5mm x 5mm ~ 7mm x 7mm Dye: 3mm</p>	<p>1064 Zoom: 1 ~ 7mm (Q-Switch, Spectra) / 2 ~ 7mm (Q-PTP, Q-3, Q-4) 532 Zoom: 0.8 ~ 6mm Collimation: 3 ~ 8mm MDF: 1064(4~8mm) / 532(3.4~6.9mm) Dye: 2~5mm</p>	<p>1064 Zoom: 1.5, 2, 3, 4, 5, 6, 7.5, 9, 10mm 532nm Zoom: 1, 1.5, 2.5, 3.5, 4.5, 5.5, 7, 8.5, 9.5mm</p>	<p>1064nm (Q-switch): 2mm to 8mm 2x2, 3x3, 4x4, 5x5, 7x7 mm² 532nm (Q-switch): 3mm to 10.5mm 2x2, 3x3, 4x4, 5x5, 7x7 mm² 1064nm (Pulsed): 2mm to 8mm 2x2, 3x3, 4x4, 5x5, 7x7 mm²</p>	<p>1) Zoom (2mm-10mm) is within range of 1064 zoom of K161670 2) Collimation (7mm) is within the range of Collimation (3~8mm) of K213567 3) MLA is within the range of predicate MDF of K213569 (both 1064nm and 532nm) 4) DOE is within the range of predicate 1064nm (Q-switch) of K202503 5) Dye (3mm) is within the range of Dye (2~5mm) of K213567</p>

<p>Laser output power</p>	<p>Genesis mode: 100 ~ 5,000 mJ 1064 nm mode: 50 ~ 1,200 mJ 1064 nm PTP mode: 600 ~ 2,000 mJ 1064 nm Triple mode: 1,000 ~ 1400 mJ 1064 nm 2x PTP mode: 1,000 ~ 1400 mJ 532 nm mode: 30 ~ 500 mJ 1064 nm DOE mode: 60 ~ 900 mJ 595 nm Dye mode: 30 ~ 250 mJ 660 nm Dye mode: 30 ~ 150 mJ</p>	<p>Spectra: Up to 1500mJ 1064nm: Up to 1200mJ 1064nm PTP: Up to 1400mJ 1064nm Q-3, Q-4: Up to 1400mJ 532nm: Up to 400mJ 585nm: Up to 250mJ 650nm: Up to 150mJ</p>	<p>Quasi-Long: Up to 3400mJ 1064nm PTP: Up to 2200mJ 532nm PTP: Up to 600mJ 1064nm: Up to 1200mJ 532nm: Up to 500mJ</p>	<p>1064nm (Q-switch): Up to 750mJ 532nm (Q-switch): Up to 250mJ 1064nm (Pulsed): Up to 4800mJ</p>	<ol style="list-style-type: none"> 1) Genesis is within the range of predicate 1064nm (Pulsed) of K202503 2) 1064nm is within the range of 1064nm of K213569 3) 1064nm PTP is within the range of predicate 1064nm PTP of K161670 4) 1064nm Triple PTP is within the range of 1064nm Q-3, Q-4 of K213569 5) 1064nm 2X PTP is within the range of 1064nm Q-3, Q-4 of K213569 6) 532nm is within the range of predicate 532nm of K161670 7) 1064nm DOE is within the range of 1064nm (Q-switch) of K202503 8) 595nm is within the range of predicate 585nm of K213569 8) 660nm is within the range of predicate 650nm of K213569
<p>Pulse width</p>	<p>532nm/1064nm mode: 5ns~12ns 1064 PTP/Triple/2X PTP: Up to 20ns Genesis mode: 80~300µs</p>	<p>Normal: 5~10ns 1064 Q-3, Q-4: 10~20ns Spectra mode: 190µs</p>	<p>1064, 532nm: 5~7ns / PTP: Up to 20ns Quasi-long: 300µs</p>	<p>1064nm (Q-switch): 6~12ns 532nm (Q-switch): 6~12ns 1064nm (Pulsed): 0.3 to 50ms</p>	<ol style="list-style-type: none"> 1) 532nm/1064nm mode is within the range of pulse width of K213569 Normal and K202503 1064nm (Q-switch) combined 2) 1064 PTP/Triple/2X PTP is within the range of K161670 PTP 2) Genesis mode is within the range of Quasi-long (300µs) of K161670
<p>Pulse repetition rate</p>	<p>Genesis mode: 1 ~ 10 Hz 1064 nm mode: 1 ~ 10 Hz 1064 nm PTP mode: 1 ~ 10 Hz 1064 nm Tripple mode: 1 ~ 10 Hz 1064 nm 2x PTP mode: 1 ~ 10 Hz 532 nm mode: 1 ~ 10 Hz 1064 nm DOE mode: 1 ~ 10 Hz 595 nm Dye mode: 1 ~ 5 Hz 660 nm Dye mode: 1 ~ 2 Hz</p>	<p>1064, 532nm: Up to 10Hz 585nm: S1, 1, 2, 5 Hz 650nm: S1, 1, 2 Hz</p>	<p>1064nm: Up to 25Hz 532nm: Up to 15Hz 1064nm PTP: Up to 15Hz 532nm PTP: Up to 15Hz 1064nm Quasi-long: Up to 25Hz</p>	<p>1064nm (Q-switch): Up to 20Hz 532nm (Q-switch): Up to 10Hz 1064nm (Pulsed): Up to 3Hz</p>	<p>Pulse repetition for all mode is within the range of K213569</p>

Max Fluence	Genesis Mode: 100J/cm ² 1064nm: 48J/cm ² 532nm: 15J/cm ²	1064nm: Up to 12 J/cm ² 532nm: Up to 6.3J/cm ²	-	1064nm (Q-switched): Up to 48 J/cm ² 532nm (Q-switch): Up to 15 J/cm ² 1064nm (Pulsed): Up to 300 J/cm ²	1) Genesis is within the range of predicate 1064nm (Pulsed) of K202503 2) 1064nm is within the range of 1064nm of K202503 3) 532nm is within the range of 532nm of K202503
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	Proposed Device	Predicate Device #1	Predicate Device #2	Predicate Device #3	SE Decision
Microbeam Handpiece	Present	Present	Absent	Present	1) The MLA and DOE Handpiece can be comparable to K213569 and K202503
Microbeam Handpiece fluence per dot	1064nm 3.2 ~ 14.5J/cm ² 532nm 1.3~ 12.1J/cm ² 1064nm DOE 1.8 ~ 13.6J/cm ²	1064nm 1.09 ~ 40.63J/cm ² 532nm 0.16 ~ 16.40J/cm ²	-	1064nm 0.03~44.4 J/cm ² (Standard) 0.2 ~16.5 J/cm ² (High Coverage) 532 nm 0.3~14.9 J/cm ² (Standard) 0.05~5.95 J/cm ² (High Coverage)	1) 1064nm is within the range of 1064nm of predicate K213569 2) 532nm is within the range of 532nm of predicated K213569 3) 1064nm DOE is within the range of 1064nm of K202503
Microbeam Handpiece Peak Power per dot *Mathematically derived value	1064nm 0.232GW 532nm 0.072GW 1064nm DOE 0.217GW	0.28GW (1064nm) 0.08GW (532nm)	-	0.3GW (1064nm) 0.083GW (532nm)	1) 1064nm is within the range of 1064nm of predicate K213569 2) 532nm is within the range of 532nm of predicated K213569 3) 1064nm DOE is within the range of 1064nm of K202503

Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Electrical Safety, Electromagnetic Compatibility Testing

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety
- IEC 60601-1-6 Edition 3.1 2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance
- IEC 60601-2-22:2007/A:2012 Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance
- IEC 60825-1 Edition 3.0 2014 Safety of laser products - Part 1: Equipment classification, and requirements
- IEC 60601-1-2:2014/A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perform

2) Software Validation

The Pastelle Pro contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.

The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005.

