November 19, 2021

SNJ Co., Ltd.
% Jongrak Kim
Director
Med.com
2202 Gongwon-ro, Guro-gu
Seoul, Seoul Teugbyeolsi 08295
Korea, South

Re: K202288
Trade/Device Name: Finebeam
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: October 14, 2021
Received: October 18, 2021

Dear Jongrak Kim:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202288

Device Name
Finebeam Dual

Indications for Use *(Describe)*
The Finebeam Dual is a surgical laser instrument intended to provide laser energy in two different operation modes (Q-switched (QSW) and long pulse (LPS)) with 1064nm or 532 nm wavelength per each function for use in a variety of dermatological procedures. Each function is intended for:
1) QSW mode with 1064nm single or 1064nm photoacoustic double pulse (PDP) function
- Removal dark ink (black, blue, and brown) tattoos;
- Treatment melasma, treatment nevus of Ota;
- Treatment common nevi;
- Removal of lightening of unwanted hair; and
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
2) QSW mode with 532nm single function
- Removal of light ink (red, tan, purple, and orange) tattoos;
- Treatment of vascular lesions including, but not limited to port-wine stains, telangiectasias, spider angioma, cherry angioma;
- Treatment of pigmented lesions including, but not limited to cafe-au-Lait birthmarks, solar lentigines, senile lentigines, Becker's nevi, freckles, common nevi, and nevus spilus;
- Treatment of seborrheic keratosis;
- Treatment of post-inflammatory hyperpigmentation; and
- Skin resurfacing procedures for the treatment of acne scars and wrinkles in the QSW mode with 532nm single function;
3) QSW mode with 1064nm Non-Q function
- Removal of unwanted hair, for stable long term or permanent hair reduction and treatment of Pseudofolliculitis Barbae (PFB). The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin;
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, cherry angioma, Hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins, Coagulation and hemostasis of soft tissue; and
- Treatment of wrinkles
4) LPS mode
- Removal of unwanted hair, for stable long term or permanent hair reduction and treatment of PFB. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin;
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins;
- Coagulation and hemostasis of soft tissue;
- Treatment of wrinkles and acne vulgaris

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 05. 510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter
   - Company Name: SNJ Co., Ltd.
   - Name: Hyang-Kee Lee
   - Address: No. 604, Ace-Techno Tower 2, Digital-ro 31-gil 19, Guro-gu, Seoul, Republic of Korea
   - Phone Number: +82-2-866-9005
   - FDA Registration Number: 3004633032
2. Application Correspondent
   - Company Name: MED.COM
   - Name: Jongrak Kim
   - Address: 2202 Gongwon-ro, Guro-gu Seoul, Republic of Korea
   - E-mail: cefdacert@gmail.com
3. Device Information
   - Model Name: Finebeam Dual
   - Common Name: Nd:YAG Laser System
   - Device Class: Class II under 21 CFR CFR 878.4810
   - Classification Name: Powered Laser Surgical Instrument
   - Product Code: GEX
4. Primary Predicate Device
   - Device Name: Fotona QX Nd:YAG/KTP Laser System Family
   - 510(k) Number: K083889
   - Manufacturer: Fotona d.d
5. Additional Predicate Devices

- Device Name: Hyperion Long Plused Nd:YAG Laser
- 510(k) Number: K132286
- Manufacturer: Laseroptek Co. Ltd.

- Device Name: StarWalker Laser System Family
- 510(k) Number: K171227
- Manufacturer: Fotona d.o.o.

- Device Name: Long pulse Nd:YAG Laser System
- 510(k) Number: K140249
- Manufacturer: Advanced Technology Laser Company, Ltd

- Device Name: Pastelle Q-Switched Nd:YAG Laser System
- 510(k) Number: K123293
- Manufacturer: WON Technology Co., Ltd.

6. Device Description

The Finebeam Dual is designed to use neodymium-doped yttrium aluminum garnet (Nd:YAG) to transform and generate high voltage sources for the optical resonator, and the atoms in the source are activated to amplify and emit laser light.

7. Indications For Use / Intended Use

The Finebeam Dual is a surgical laser instrument intended to provide laser energy in two different operation modes (Q-switched (QSW) and long pulse (LPS)) with 1064nm or 532 nm wavelength per each function for use in a variety of dermatological procedures. Each function is intended for:

1) QSW mode with 1064nm single or 1064nm photoacoustic double pulse (PDP) function
   - Removal dark ink (black, blue, and brown) tattoos;
   - Treatment melasma, treatment nevus of Ota;
   - Treatment common nevi;
   - Removal of lightening of unwanted hair; and
   - Skin resurfacing procedures for the treatment of acne scars and wrinkles
2) QSW mode with 532nm single function

- Removal of light ink (red, tan, purple, and orange) tattoos;
- Treatment of vascular lesions including, but not limited to port-wine stains, telangiectasias, spider angioma, cherry angioma;
- Treatment of pigmented lesions including, but not limited to cafe-au-Lait birthmarks, solar lentigines, senile lentigines, Becker's nevi, freckles, common nevi, and nevus spilus;
- Treatment of seborrheic keratosis;
- Treatment of post-inflammatory hyperpigmentation; and
- Skin resurfacing procedures for the treatment of acne scars and wrinkles in the QSW mode with 532nm single function;

3) QSW mode with 1064nm Non-Q function
   - Removal of unwanted hair, for stable long term or permanent hair reduction and treatment of Pseudofolliculitis Barbae (PFB). The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin;
   - Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, cherry angioma, Hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins, Coagulation and hemostasis of soft tissue; and
   - Treatment of wrinkles

4) LPS mode
   - Removal of unwanted hair, for stable long term or permanent hair reduction and treatment of PFB. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin;
   - Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins;
   - Coagulation and hemostasis of soft tissue;

8. Summary of Technological Characteristics

The Finebeam Dual has the same technological and design characteristics (design, chemical composition, energy source; wavelength, active medium, cooling system, power supply, beam delivery, controls, housing) as the previously cleared devices. The output characteristics are for the intended use the same as those of the predicate devices. All

systems are based on variable pulse duration power supply technology. All lasers utilize class I aiming beams which pose no hazard to the user. All systems are microprocessor controlled devices. The microprocessor control regulates normal operation, permits parameter selection, and avoids hazard incidence. All systems utilize an internal closed loop water-air heat exchanger circuit for optimal thermal control of the laser cavity. The risk and benefits for the Finebeam Dual are identical to the predicate devices when used for similar clinical applications.

A comparison of the technical specifications for the intended use of the Finebeam Dual with the previously cleared devices is provided the table in section 10.

Non-Clinical Test Conclusion

Nonclinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2005/A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010/A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-22:2014 Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements

9. Comparison of technological characteristics with the predicate device

9.1. Intended use comparison of 532nm single and 1064nm single function in the Q-switched mode

Device Name	Fotona QX Nd:YAG/KTP Laser System Family (Predicate)	Finebeam (Proposed)
Product Code	GEX	Same
Regulation Number	21 CFR 878.4810	Same
K number	K083889	K202288
Applicant	Fotona d.o.o.	SNJ Co., Ltd.
Wavelength	1064nm and 532nm	Same
Intended use	1064 nm wavelength in Q-switched mode: - Removal of dark ink (black, blue and brown) tattoos - Treatment melasma - Treatment of nevus of Ota - Treatment of common nevi - Removal or lightening of unwanted hair - Skin resurfacing procedures for the treatment of acne scars and wrinkles 532 nm wavelength in Q-switched mode (nominal delivered energy of 585 nm and 650 nm with the optional 585 nm and 650 nm dye converter handpieces): - Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos	With 1064nm single or 1064nm PDP function - Removal dark ink (black, blue and brown) tattoos - Treatment melasma - Treatment nevus of Ota - Treatment common nevi - Removal of lightening of unwanted hair - Skin resurfacing procedures for the treatment of acne scars and wrinkles With 532nm single function - Removal of light ink (red, tan, purple, and orange) tattoos - Treatment of vascular lesions including, but not limited to port-wine stains, telangiectasias, spider angioma, cherry angioma

Device Name	Fotona QX Nd:YAG/KTP Laser System Family (Predicate)	Finebeam (Proposed)
	- Treatment of vascular lesions including, but not limited to: - port wine birthmarks - telangiectasias - spider angioma - Cherry angioma - Spider nevi - Treatment of pigmented lesions including, but not limited to: - cafe-au-Iait birthmarks - solar lentigines - senile lentigines - Becker's nevi - freckles - common nevi - nevus spilus - Treatment of seborrheic keratosis - Treatment of post inflammatory hyperpigmentation - Skin resurfacing procedures for the treatment of acne scars and wrinkles.	- Treatment of pigmented lesions including, but not limited to cafe-au-Lait birthmarks, solar lentigines, senile lentigines, Becker's nevi, freckles, common nevi, and nevus spilus - Treatment of seborrheic keratosis - Treatment of post-inflammatory hyperpigmentation - Skin resurfacing procedures for the treatment of acne scars and wrinkles

9.2. Intended use comparison of Non-Q-Switched function in the Q-Switched mode

Device Name	Fotona QX Nd:YAG/KTP Laser System Family (Predicate)	Finebeam (Proposed)
Product Code	GEX	Same

Device Name	Fotona QX Nd:YAG/KTP Laser System Family (Predicate)	Finebeam (Proposed)
Regulation Number	21 CFR 878.4810	Same
K number	K083889	K202288
Applicant	Fotona d.o.o.	SNJ Co., Ltd.
Wavelength	1064nm	Same
Intended use	1064 nm wavelength in non-Q-switched mode: - 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 - Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to,port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins - Coagulation and hemostasis of soft tissue - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris	With 1064nm Non-QSW function - Removal of unwanted hair, for stable long term or permanent hair reduction and treatment of PFB (Pseudofolliculitis Barbae). The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin - Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, cherry angioma, Hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins - Coagulation and hemostasis of soft tissue - Treatment of wrinkles

9.3. Intended use comparison of PDP function in the QSW mode

Device Name	Pastelle Q-Switched Nd:YAG Laser System (Predicate)	Finebeam (Proposed)
Product Code	GEX	Same
Regulation Number	21 CFR 878.4810	Same

Device Name	Pastelle Q-Switched Nd:YAG Laser System (Predicate)	Finebeam (Proposed)
K number	K123293	K202288
Applicant	WON Technology Co., Ltd.	SNJ Co., Ltd.
Wavelength	1064nm and 532nm	Same
Intended use	1064 nm wavelength in PTP mode: - Removal of dark ink (black, blue and brown) tattoos - Treatment of melasma - Treatment of nevus of Ota - Treatment of common nevi - Removal or lightening of unwanted hair - Skin resurfacing procedures for the treatment of acne scars and wrinkles	With 1064nm PDP function - Removal of dark ink (black, blue and brown) tattoos - Treatment of melasma - Treatment of nevus of Ota - Treatment of common nevi - Removal or lightening of unwanted hair - Skin resurfacing procedures for the treatment of acne scars and wrinkles

9.4. Intended use comparison of LPS mode

Device Name	Fotona XP Nd:YAG Laser System Family	Family of CoolGlide Aesthetic Lasers	Finebeam (Proposed)
Product Code	GEX	Same	Same
Regulation Number	21 CFR 878.4810	Same	Same
K number	K090126	K132185	K202288
Applicant	Fotona d.o.o.	Cutera, Inc.	SNJ Co., Ltd.
Wavelength	1064nm	Same	Same
Intended use	- Removal of unwanted hair, for stable long term or permanent hair reduction and	1064 nm wavelength in long pulse mode:	1064 nm wavelength in long pulse mode:

Device Name	Fotona XP Nd:YAG Laser System Family	Family of CoolGlide Aesthetic Lasers	Finebeam (Proposed)
	for treatment of PFB. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. - Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, hemangiomas, warts, telangiectasias, rosacea, leg veins and spider veins. - Coagulation and hemostasis of soft tissue. - Incision/excision of soft body tissue in dermatology. - Soft tissue general surgery applications-skin incision; tissue dissection; cornpelte or partial resection of internal organs, tumors, lesions; tissue ablation; vessel coagulation. - Benign pigmented lesions such as, but not limited to: lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic	- Coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasias, rosacea, venus lake, leg veins, spider veins and poikilodlerma of civatte; and treatment of benign cutaneous lesions such as, but not limited to, warts, scars, striae and psoriasis. The lasers are 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, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques. - Pigmented lesions to reduce lesion size, for patients with	- Removal of unwanted hair, for stable long term or permanent hair reduction and treatment of PFB. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. - Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, hemangiomas, warts, telangiectasias, rosacea, leg veins, and spider veins. - Coagulation and hemostasis of soft tissue. - Incision/excision of soft body tissue. - Treatment of wrinkles and acne vulgaris

Device Name	Fotona XP Nd:YAG Laser System Family	Family of CoolGlide Aesthetic Lasers	Finebeam (Proposed)
	keratosis, nevi, chloasma (melisma), verruca, skin tags, keratosis, tattoo (significant reduction in the intensity of black and/or blue-black tattoo) and plaques. - Treatment of wrinkles and acne vulgaris.	lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. - Treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. - Temporary and permanent hair reduction. 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. - Also indicated for the treatment for pseudofolliculitis barbae (PFB) - Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. - All skin types (Fitzpatrick I-VI), including tanned skin.	

Device Name	Fotona XP Nd:YAG Laser System Family	Family of CoolGlide Aesthetic Lasers	Finebeam (Proposed)
		- Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laparoscopy, gastroenterology, general surgery, head and necklotorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.	

9.5. Technical characteristics comparison

- Q-Siwtch mode

Predicate	Fotona QX Nd:YAGIKTP Laser System Family	Pastelle Q-Switched Nd:YAG Laser System	Finebeam
Product Code	GEX	Same	Same
Regulation Number	21CFR 878.4810	Same	Same
K number	K083889	K123293	K202288
Applicant	Fotona d.o.o.	WON Technology Co., Ltd.	SNJ Co., Ltd.

Predicate	Fotona QX Nd:YAGIKTP Laser System Family	Pastelle Q-Switched Nd:YAG Laser System	Finebeam
Laser type	Nd:YAG Laser	Same	Same
Wavelength	532nm and 1064nm	Same	Same
Pulse frequency	up to 10 Hz	1-10 Hz	1-10 Hz
Pulse duration	1064nm Q-switched mode: 5-20ns 532nm Q-switched mode: 5-20ns non-Q switched mode: 0.25ms	Q-switched Mode: 4 to 48 ns Genesis Mode (Non-Q): 0.08 - 0.48ms	1064 single (Q-switched mode): < 25ns 532 single (Q-switched mode): < 25ns PDP mode: < 25ns non-Q switched mode: 0.3ms
Energy (max)	1600mJ at 1064nm 600mJ at 532nm 5000mJ at Non-Q mode	1300mJ at 1064nm 500mJ at 532nm 1600mJ at PTP 3500mJ at Non-Q mode	1600mJ at 1064nm 500mJ at 532nm 2200mJ at PTP 3500mJ at Non-Q
Spot size	- R28 Handpiece : 1064nm = 2 ~ 8 mm : 532nm = 2 ~ 8 mm - R585, 650 Handpiece : 585nm = 2 ~ 4 : 650nm = 2 ~ 4	- Zoom Handpiece : 1064 nm, 532 nm = 2~10 mm - Collimator Handpiece : 1064 nm = 8 mm - Fractional Handpiece (Option) : 1064 nm = unknown the size per spot Area: 5x5 mm^2 (DOE, Diffractive optical element), Spacing between micro spot: unknown	- Zoom Handpiece : 1064 nm = 2~10 mm : 532 nm = 1~7 mm - Collimator Handpiece : 1064 nm = 8 mm
Aiming laser	650nm diode laser (<5mW), Class III	650nm diode laser (<5mW), Class III	655nm diode laser (<5mW), Class III
Beam Delivery	Articulated arm	same	same

Predicate	Fotona QX Nd:YAGIKTP Laser System Family	Pastelle Q-Switched Nd:YAG Laser System	Finebeam
User interface	Push button control	LCD Touch screen	LCD Touch screen

- Long Pulse mode

Predicate	Fotona XP Nd:YAG Laser System Family	Family of CoolGlide Aesthetic Lasers	Finebeam
Product Code	GEX	Same	Same
Regulation Number	21CFR 878.4810	Same	Same
K number	K090126	K132185	K202288
Applicant	Fotona d.o.o.	Cutera, Inc.	SNJ Co., Ltd.
Laser type	Nd:YAG Laser	Same	Same
Wavelength	1064nm	1064 nm	532nm and 1064nm
Pulse frequency	up to 75 Hz	1-10 Hz and single shot	1-10 Hz
Pulse duration	0.1-300ms	0.1-300ms	Long Pulse mode: 0.5-300ms
Energy (max)	Up to 120 J	up to 300J/cm2	60J at LPS (Long pulse)
Spot size	R33 Handpiece : 2 - 10 mm R34 Handpiece : 15 - 20 mm	Integrated 3, 5, 8, 10 mm	- Zoom Handpiece : 1064 nm = 2~10 mm : 532 nm = 1~7 mm - Collimator Handpiece : 1064 nm = 8 mm
Aiming laser	650nm diode laser (<5mW), Class III	630-680 nm	655nm diode laser (<5mW), Class III

Predicate	Fotona XP Nd:YAG Laser System Family	Family of CoolGlide Aesthetic Lasers	Finebeam
Beam Delivery	Optical fiber	Optical fiber	Articulated arm
User interface	Push button control	Push button control	LCD Touch screen

10. Comparison discussion

10.1. Intended use

Each device is intended for use of surgical laser device in Dermatology.

10.2. Technological characteristics

The Finebeam Dual has the same technological and design characteristics as the previously cleared devices. The output characteristics are for the intended use the same as those of the predicate devices. All systems are based on variable pulse duration power supply technology. All lasers utilize class I aiming beams which pose no hazard to the user. All systems are microprocessor controlled devices. The microprocessor control regulates normal operation, permits parameter selection and avoids hazard incidence. All systems utilize an internal closed-loop water-air heat exchanger circuit for optimal thermal control of the laser cavity. The risk and benefits for the Finebeam Dual are identical to the predicate devices when used for similar clinical applications.

10.3. Performance characteristics

Finebeam Dual is designed, tested, and manufactured per both mandatory and voluntary standards.

11. Conclusion

Based on the data submitted in this 510(k) submission, the Finebeam Dual is substantially equivalent in terms of intended use, technological characteristics, and performance to the predicate device. The proposed device, Long Pulse Nd:YAG Laser System,

is determined to be Substantially Equivalent (SE) to the predicate device, XP Nd:YAG Laser System and CoolGlide Aesthetic Lasers, in respect of safety and effectiveness.