December 19, 2025

Wontech Co., Ltd.
Hyunsik Yoon
Regulatory Affairs Team General Manager
64, Techno 8-Ro, Yuseong-Gu
64, Techno 8-Ro, Yuseong-Gu, 34028
Republic Of Korea

Re: K252877
Trade/Device Name: SANDRO Dual
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: September 10, 2025
Received: September 10, 2025

Dear Hyunsik 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: 2025.12.19 13:12:16 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252877

Device Name
SANDRO Dual

Indications for Use *(Describe)*
The SANDRO Dual Laser System is indicated for the following at the specified wavelength:
755nm
Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. 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. On all skin types (Fitzpatrick I - VI) including tanned skin.
Treatment of benign pigmented lesions.
Treatment of wrinkles.
The photocoagulation of dermatological vascular lesions (such as pant-wine stains, hemangiomas, telangiectasias)

1064nm
Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. 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. 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, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.

The laser is indicated for 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. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles.

1064nm
Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)

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 (K252877)

[As required by 21 CFR 807.92]

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

December 4, 2025

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

- Name of Manufacturer: WONTECH 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 and Alexandrite laser combination laser system
Trade name: SANDRO Dual

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, parts 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: K201111
- Applicant: Candela Corporation

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- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Trade Name: GentleMAX Pro Plus

Predicate device 2

- 510(k) Number: K231791
- Applicant: Illoda Co., Ltd.
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Trade Name: PENTO Nd:YAG and Alexandrite Laser System

Predicate device 3

- 510(k) Number: K200110
- Applicant: WONTECH CO.,LTD.
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Trade Name: SANDRO Dual

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

The SANDRO Dual laser system consists of laser resonator, touch screen monitor, optical fiber with handpiece, and foot switch.

1) Nd:YAG Laser
A certain amount of electric power set by the LCD monitor is permitted to the laser resonator through the power supply. Then, the laser resonator delivers the electrical energy to the flash lamp which converts the electrical energy into the light source. This concentrated light source is radiated on the medium of Nd:YAG, resulting in the laser energy source. The laser energy generated by the medium of Nd:YAG is converted to the heat energy once it gets to human skin surface and used for a variety of medical purpose such as an ablation, incision and removal of targeted tissue.

2) Alexandrite Laser
A certain amount of electric power set by the LCD monitor is permitted to the laser resonator through the power supply. Then, the laser resonator delivers the electrical energy to the flash lamp which converts the electrical energy into the light source. This concentrated light source is radiated on the medium of Alexandrite, resulting in the ultimate laser energy source. The laser energy generated by the medium of Alexandrite is converted to the heat energy once it gets to human skin surface and used for a variety of medical purpose such as an ablation, incision and removal of targeted tissue.

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6. Statement of intended use [21 CFR 807.92(a)(5)]

The SANDRO Dual Laser System is indicated for the following at the specified wavelength:

755nm
Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. 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. On all skin types (Fitzpatrick I - VI) including tanned skin.

Treatment of benign pigmented lesions.
Treatment of wrinkles.
The photocoagulation of dermatological vascular lesions (such as pant-wine stains, hemangiomas, telangiectasias)

1064nm
Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. 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. 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, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.

The laser is indicated for 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.
Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
Treatment of wrinkles.

1064nm
Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)

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

The technical characteristics of subject device are the same as the predicate device. It is substantially equivalent to this device in design, function, and technical characteristic

	Proposed Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	SE decision
K Number	To be assigned	K201111	K231791	K200110	-
Manufacturer	WON TECH Co., Ltd.	Candela Corporation	Illoda Co., Ltd.	WON TECH Co., Ltd.	-
Model	SANDRO Dual	GentleMAX Pro Plus	PENTO Nd:YAG and Alexandrite laser system	SANDRO Dual	-
Product Code	GEX	GEX	GEX	GEX	Same
Indications for Use	The SANDRO Dual Laser System is indicated for the following at the specified wavelength: 755nm Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. 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. On all	The GentleMAX Family of Laser Systems is indicated for the following at the specified wavelength: 755nm Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. 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. On all	The PENTO Nd:YAG and Alexandrite laser system in indicated for : the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. 755nm Wavelength: - Temporary hair reduction. - Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. - Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. - Permanent hair reduction is defined as the long-term, stable reduction in the number ofhairs regrowing when	The SANDRO Dual Laser System is indicated for the following at the specified wavelength: 755nm Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. 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. On all skin	Same

	Proposed Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	SE decision
	skin types (Fitzpatrick I - VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles. The photocoagulation of dermatological vascular lesions (such as pant-wine stains, hemangiomas, telangiectasias) <u>1064nm</u> Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. 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. 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, hemangioma, warts, telangiectasia, rosacea,	skin types (Fitzpatrick [- VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles. The photocoagulation of dermatological vascular lesions (such as pant-wine stains, hemangiomas, telangiectasias) <u>1064nm</u> Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. 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. 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, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider	measured at 6, 9, and 12 months after the completion of a treatment regime. - On all skin types (Fitzpatrick I- VI) including tanned skin. - Treatment of benign pigmented lesions. Treatment of wrinkles. - The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias). 1064nm Wavelength: - Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. - 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. - 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, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider	types (Fitzpatrick [- VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles. The photocoagulation of dermatological vascular lesions (such as pant-wine stains, hemangiomas, telangiectasias) <u>1064nm</u> Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. 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. 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, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue.	

	Proposed Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	SE decision
	venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques. The laser is indicated for 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. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles. <u>1064nm</u>	veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques. The laser is indicated for 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. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles. <u>1064nm</u> Temporary increase of clear nail in patients with onychomycosis (e.g.,	veins. - Coagulation and hemostasis of soft tissue. - Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques. - The laser is indicated for 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. - Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. - Treatment of wrinkles. - Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.	Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques. The laser is indicated for 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. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles. <u>1064nm</u> Temporary increase of clear nail in patients with onychomycosis (e.g., derniatophytes, Trichophyton rubrum and T.mentagrophytes,	

	Proposed Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	SE decision
	Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)	dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)		and for yeast Candida Albicans, etc.)	
Wavelength	755nm / 1064nm	755nm / 1064nm	755nm / 1064nm	755nm / 1064nm	Same
Laser Output	755nm: 60J 1064nm: 90J	755nm: 68J 1064nm: 90J	755nm: 60J 1064nm: 80J	755nm: 50J 1064nm: 80J	Same
Radiation Diameter	2, 3, 5, 8, 10, 12, 15, 18, 20, 22, 25mm	1.5 mm, 3 mm, 3x10 mm, 5 mm, 6 mm, 8 mm, 10 mm, 12 mm, 15 mm, 18 mm, 20 mm, 22 mm, 24 mm, 26 mm	3, 6, 8, 10, 12, 15, 18mm (Option: 5, 20, 22, 24mm)	2, 3, 5, 8, 10, 12, 15, 18, 20 mm	All range of the spot size is included in the predicate devices. As the maximum spot size of predicate device 1 is greater than the proposed devices, it seems safe and effective.
Pulse Duration	0.2ms – 300ms	0.25ms - 100ms	0.25ms - 300ms	0.3ms – 100ms	Same as Predicate 2
Repetition Rate	0.5 ~ 10Hz	Max. 10Hz	Max. 10Hz	0.5 ~ 10Hz	Same

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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 SANDRO Dual contains basic documentation. 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: Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff (2023).

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3) Biocompatibility

Part	Material	Patient Contact	Duration of Contact by ISO 10993-1	Bio-compatibility
Handpiece Tip	Aluminium Powder (Cas No. 7429-90-5)	Intact Skin	Limited (< 24 hours)	Yes

ISO 10993-5 "Test For In Vitro Cytotoxicity" (2009 Edition)
ISO 10993-10 "Test for irritation and skin sensitization : guinea pig Maximization test" (2010 Edition)
ISO 10993-10 "Tests for irritation and skin sensitization 'Animal Irritation Test" (2010 Edition)

4) Performance Testing

The performance of the device has been validated as follows.

- Laser wavelength: 755nm, 1064nm
- Laser output power: Max 90J
- Pulse /duration: 0.2ms – 300ms
- Pulse frequency: 0.5-10Hz

Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification WONTECH Co., Ltd. concludes that the SANDRO Dual is substantially equivalent to the predicate device as described herein.