May 26, 2021

WON TECH Co., Ltd.
Lana Hong
Staff of Regulatory Affairs
64 Techno 8-Ro, Yuseong-gu
Daejeon, 34028
Korea, Republic Of

Re: K200110
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

Dear Lana Hong:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter for your device cleared on March 16, 2020. Specifically, FDA is updating this SE Letter due to the clearance date not appearing on the original letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Assistant Director, Neil Ogden, at 301-796-6397 or neil.ogden@fda.hhs.gov.

Sincerely,

Neil R.P. Ogden

Digitally signed by Neil R.P. Ogden
Date: 2021.05.26 16:04:49 -04'00'

Neil R.P. Ogden
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

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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: January 13, 2020
Received: January 17, 2020

Dear Lana Hong:

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 and Part 809); 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,

Jessica Mavadia-shukla -S

Jessica Mavadia-Shukla, Ph.D.
Acting 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)*
K200110

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 benign vascular lesions (such as port-wine stains, hemangiomas, telangiectasias)

1064nm
Removal of unwanted hair, for stable long term or permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of 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. Benign pigmented and/or benign vascular lesions, such as, but not limited to port-wine stains, telangiectasia, venus lake, leg veins and spider veins. Benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, skin tags, keratosis.
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.)

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 5. 510(k) Summary

510(k) Summary

[As required by 21 CFR 807.92]

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

January 13, 2020

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

- Name of company: WON TECH Co., Ltd.
- Address: 64 Techno 8-Ro, Yuseong-gu, Daejeon, Republic of Korea, 34028
- Contact Name: Lana Hong/ Staff of Regulatory Affair
- Telephone No.: +82-70-7836-6970
- Fax No.: +82-70-934-9491
- Email Address: regulatory@wtlaser.com

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

Trade Name	SANDRO Dual
Common Name	Dermatology Laser System
Device Classification Name	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810, Product Code GEX)
Regulation Number	21 CFR 878.4810
Classification Product Code	GEX
Device Class	Class II
510k Review Panel	General & Plastic Surgery

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

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

- 510(k) Number: K140122
- Applicant: Candela Corporation
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR878.4810, Product Code GEX)
- Trade Name: GentleMAX Family of Laser Systems

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

The SANDRO Dual is a Nd:YAG and Alexandrite laser operating at wavelengths of 1,064 nm and 755 nm. The SANDRO Dual consists of the main body, optical fiber cable, handpiece, handpiece tip, footswitch, and handpiece cable holder. The laser output is delivered to the skin through the optical fiber terminated by the handpiece. The SANDRO Dual laser system is used for a variety of medical purpose such as an ablation, incision and removal of targeted tissue. For treatment, the user can select the appropriate fluence value. The energy is changed automatically in accordance with the selected fluence value and selected spot size. The user can change the fluence value by pressing UP and/or DOWN button from the LCD display/Touch Pad located on the front of the main unit.

6. Indications for 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 benign vascular lesions (such as port-wine stains, hemangiomas, telangiectasias)

1064nm

Removal of unwanted hair, for stable long term or permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after

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the completion of a treatment regime. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Benign pigmented and/or benign vascular lesions, such as, but not limited to port-wine stains, telangiectasia, venus lake, leg veins and spider veins. Benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, skin tags, keratosis.

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.)

7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences in the technological characteristics of this device compared to the predicate device which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the SANDRO Dual and the predicate devices:

	Proposed Device	Predicate Device	SE decision
K Number	K200110	K140122	-
Manufacturer	WON TECH Co., Ltd.	Candela Corporation	-
Model	SANDRO Dual	GentleMAX Family of Laser Systems	-
Product Code	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 skin types (Fitzpatrick I- VI) including tanned skin.	The GentleMAX Family of Laser Systems is indicated for the following at the specified wavelength: <u>755nm</u> 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	Same

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	Proposed Device	Predicate Device	SE decision
	Treatment of benign pigmented lesions. Treatment of wrinkles. The photocoagulation of dermatological benign vascular lesions (such as port-wine stains, hemangiomas, telangiectasias) 1064nm Removal of unwanted hair, for stable long term or permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of 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. Benign pigmented and/or benign vascular lesions, such as, but not limited to port-wine stains, telangiectasia, venus lake, leg veins and spider veins. Benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, skin tags, keratosis. 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.)	(Fitzpatrick [- 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) <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. 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	

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	Proposed Device	Predicate Device	SE decision
		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., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)	
Laser Type	Flash lamp-excited, Solid state Alexandrite and Nd:YAG laser	Flash lamp-excited, Solid state Alexandrite and Nd:YAG laser	Same
Wavelength	755nm / 1064nm	755nm / 1064nm	Same
Laser Output	755nm: Max. 50J 1064nm: Max. 80J	755nm: Max. 50J 1064nm: Max. 80J	Same
Spot Size	2, 3, 5, 7, 10, 12, 15, 18, 20mm	1.5, 3, 6, 8, 10, 12, 15, 18 mm	No new issues on safety and effectiveness
Pulse Duration	0.3ms - 100ms	0.25ms - 100ms	Same
Repetition Rate	0.5 ~ 10Hz	Max. 10Hz	Same
Aiming Beam	532 nm, 5mW(Average)	520 nm to 550 nm, less than 8 mW	No other issue of safety and effectiveness because the Energy output delivered to the patient is at the

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	Proposed Device	Predicate Device	SE decision
			same level compared to the same.
Electrical consumption	220-230V~, 50/60Hz, Single phase	200-240V~, 50/60 Hz, single phase	Same
Pulse control method	Footswitch	Footswitch	Same
Skin cooling method	SCS: Skin Cooling Spray	DCD: Dynamic Cooling Device	No new issues on safety and effectiveness
Dimensions (W x L x H)	460 mm × 978 mm × 1110 mm	42"x 18" x 27" (inch) (1067 x 457 x 686 mm)	No new issues on safety and effectiveness
Weight	110 kg	260 lbs (118 kg)	No new issues on safety and effectiveness

The difference in maximum spot size does not raise any new safety and effectiveness issues because the SANDRO Dual has the same wavelength, repetition rate and energy output delivered to the patient are at the same level compared to the predicate device. The differences between SANDRO Dual and the predicate device in regard to skin cooling method, weight and dimensions do not raise any new safety and effectiveness issues.

Verification and validation activities were conducted to establish the performance and safety characteristics of the SANDRO Dual. The results of these activities show that there are no any new safety and effectiveness issues. Therefore, the SANDRO Dual is considered substantially equivalent to the predicate device.

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

1) Electrical Safety, Electromagnetic Compatibility and Performance.

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:

Standards No.	Standards Organization	Standard Title	Version	Publication Year
ES60601-1	AAMI	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	Edition 3.1	2016
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	Edition 4	2018
60601-2-22	IEC	Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment	Edition 3	2019

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Standards No.	Standards Organization	Standard Title	Version	Publication Year
60825-1	IEC	Safety of Laser Products - Part 1: Equipment Classification, and Requirements	Edition 3	2019

2) Software Validation

The SANDRO Dual contains MODERATE level of concern software. The 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.

3) Biocompatibility

According to the recommendations of ISO 10993-1 and FDA Blue Book Memo #G95-1, the following tests were performed:

- Cytotoxicity test according to ISO 10993-5:2009
- Intracutaneous (intradermal) reactivity test according to ISO 10993-10:2010
- Skin sensitization test according to ISO 10993-10:2010

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

No clinical studies were considered necessary and performed.

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

The SANDRO Dual has the same intended uses, utilize similar operating principles, and match key design aspects, including similar spot size, the same wavelengths and the variable delivered fluence in comparison to the predicate device. On the basis of similarities in method of operation, intended uses, and key technical characteristics, WON TECH Co., Ltd., believes that the SANDRO Dual is substantially equivalent to the predicate device. In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification WON TECH Co., Ltd., concludes that the SANDRO Dual is substantially equivalent in safety and effectiveness to the predicate device as described herein.