September 5, 2019

Won Tech Co., Ltd.
Jake Yu
Staff of Regulatory Affairs
64 Techno 8-Ro, Yuseong-gu
Daejeon, 34028 Kr

Re: K183563
Trade/Device Name: Holinwon 30
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: July 17, 2019
Received: August 6, 2019

Dear Jake Yu:

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 (Acting)
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)*
K183563

Device Name
Holinwon 30

Indications for Use *(Describe)*
The Holinwon 30 laser system is indicated for superficial incision, excision, resection, ablation, coagulation, hemostasis, and vaporization, with or without an endoscope, in the following indications.

1) Dermatology and Plastic Surgery of soft, mucosal, fatty, and cartilaginous tissues, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including: scars, basal cell carcinomas, tattoo removal, lesions of skin and subcutaneous tissue, vascular lesions (including port wine stains, hemangioma, telangiectasia [facial, leg], and rosacea), plantar warts, periungual and subungual warts, corns, debridement of decubitus ulcer, papillomas and skin tag vaporization.

2) Gastroenterological/GastrointestinaI Surgery, including: Cholecystectomy, varices, lysis of adhesions, esophagitis, appendectomy, esophageal ulcer, biopsy Mallory-Weiss tear, pylorostenotomy, gastric ulcer, benign and malignant lesions, duodenal ulcer, rectal polyps of sigmoid colon, non-bleeding ulcer, gall bladder calculi, gastric erosions, biliary/ bile duct calculi, colorectal cancer, benign and malignant neoplasm, gastritis, polyps, bleeding tumors, colitis, pancreatitis, ulcers, vascular malformations, angiodysplasia, telangiectasias, hemorrhoids and telangiectasias of the Osler-Weber-Rendu disease.

3) General Surgery of soft tissue, including: skin incision, herniorrhaphy, tissue dissection, tonsillectomy, excision of external tumors and lesions, lymphadenectomy, complete or partial resection of internal organs, partial nephrectomy, tumors and lesions, pilonidal cystectomy, tissue ablation, resection of lipoma, mastectomy, pelvic adhesiolysis, hepatectomy, debridement of decubitus ulcer, pancreatectomy, hemorrhoids, splenectomy, pilodidal cyst removal and repair, thyroidectomy, debridement of statis ulcer, parathyroidectomy and biopsy.

4) Genitourinary Surgery/Urology, including: superficial urinary bladder tumors, urethral and penile hemangioma, invasive bladder carcinoma, bladder neck obstructions, urethral strictures, holmium laser incision/excision/resection/ ablation, hemoastasis, vaporization, and enucleation in the treatment of benign prostatic hyperplasia (BPH), lesions of the external genitalia, bladder, urethral and ureteral tumors and condylomas.

5) Gynecological Surgery during open and endoscopic procedures, including: condyloma acuminata

6) Lithotripsy and Percutaneous Urinary Lithotripsy, including: fragmentation of urinary calculi, fragmentation of kidney calculi, fragmentation of urethral calculi, treatment of distal impacted fragment of steinstrasse when guide wires cannot be passed

7) Orthopedic Surgery in pathological soft and cartilaginous tissue in small and large joints, including: knee meniscectomy, ligament and tendon release, knee synovectomy, contouring and sculpting of articular surfaces, chondromalacia and tears, debridement of inflamed synovial tissue, loose body debridement, capsulectomy in the knee, lateral retinacular release, chondroplasty in the knee, debridement of the degenerative knee, chondromalacia ablation and plica removal

8) Otorhinolaryngology (ENT) Surgery in soft, mucosal, cartilaginous and bony tissue, including: endosinus surgery, polypectomy, functional endoscopic sinus surgery, maxillary antrostomy, turbinate procedures (e.g.. turbinectomy), frontal sinusotomy, dacryocystorhinostomy (DCR), sphenoidotomy and ethmoidectomy

9) Percutaneous Cervical, Lumbar, and Thoracic Disc Decompression / Discectomy: Superficial incision, excision, resection, ablation, coagulation, hemostasis and vaporization, with or without an endoscope, in the following:
-Percutaneous Lumbar Disc Decompression/Discectomy in soft, cartilaginous, and bony tissue, including: foraminoplasty
-Percutaneous Cervical Disc Decompression/Discectomy in soft tissue, in patients with: uncomplicated ruptured or herniated discs,
neck pain with radiation down the arm,
symptoms and signs of sensory loss, tingling, numbness, muscle weakness, and/or decreased deep tendon reflexes,
MRI, CT, myelogram, or discogram findings of disc herniation consistent with patient signs and symptom,
positive electromyography and/or nerve conduction studies,
no improvement after 12 weeks of conservative therapy (i.e., physical therapy, traction, bed rest, exercises, and medication)
-Percutaneous Thoracic Disc Decompression/Discectomy in soft tissue, in patients with:
uncomplicated ruptured or herniated discs,
thoracic and intercostal intractable pain,
paresthesias at levels appropriate to the herniated discs visualized on MRI and CTmyelography,
MRI, CT, myelogram, or discogram findings of disc herniation consistent with patient signs and symptoms,
no improvement after 12 weeks of conservative therapy (i.e., physical therapy, traction, bed rest, exercises, and medication)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1-6. 510(k) Summary K183563

510(k) Summary

[As required by 21 CFR 807.92]

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

September 1, 2019

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

- Name of Sponsor: WON TECH Co., Ltd.
  - Address: 64 Techno 8-Ro, Yuseong-gu, Daejeon, Republic of Korea, 34028
- Contact Name: Jake Yu/ Staff of Regulatory Affair
  - Telephone No.: +82-70-7836-6921
  - Fax No.: +82-70-934-9491
  - Email Address: regulatory@wtlaser.com
- Registration No.: 3006985208
- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

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

Trade Name	Holinwon 30
Common Name	Holmium Laser System
Device Classification Name	Powered Laser Surgical Instrument
Regulation Number	21CFR878.4810
Classification Product Code	GEX
Device Class	Class II
510k Review Panel	General & Plastic Surgery

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

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

Primary Predicate device

- 510(k) Number: K041660
- Applicant: Trimedyne.Inc.
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: OmniPulse Jr.™

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

The Holinwon 30 Laser System is a pulsed solid-state Holmium:YAG laser system is designed to deliver infrared laser energy with a wavelength of 2100 nm and a nominal pulse width of 600 microseconds. Menu driven control options allows the operator to select the pulse energy and the pulse repetition rate(frequency).

4. Indications for Use [21 CFR 807.92(a)(5)]

The Holinwon 30 laser system is indicated for superficial incision, excision, resection, ablation, coagulation, hemostasis, and vaporization, with or without an endoscope, in the following indications.

1) Dermatology and Plastic Surgery of soft, mucosal, fatty, and cartilaginous tissues, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including: scars, basal cell carcinomas, tattoo removal, lesions of skin and subcutaneous tissue, vascular lesions (including port wine stains, hemangioma, telangiectasia [facial, leg], and rosacea), plantar warts, periungual and subungual warts, corns, debridement of decubitus ulcer, papillomas and skin tag vaporization.

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Cholecystectomy, varices, lysis of adhesions, esophagitis, appendectomy, esophageal ulcer, biopsy Mallory-Weiss tear, pylorostenotomy, gastric ulcer, benign and malignant lesions, duodenal ulcer, rectal polyps of sigmoid colon, non-bleeding ulcer, gall bladder calculi, gastric erosions, biliary/bile duct calculi, colorectal cancer, benign and malignant neoplasm, gastritis, polyps, bleeding tumors, colitis, pancreatitis, ulcers, vascular malformations, angiodysplasia, telangiectasias, hemorrhoids and telangiectasias of the Osler-Weber-Rendu disease.

3) General Surgery of soft tissue, including:
skin incision, herniorrhaphy, tissue dissection, tonsillectomy, excision of external tumors and lesions, lymphadenectomy, complete or partial resection of internal organs, partial nephrectomy, tumors and lesions, pilonidal cystectomy, tissue ablation, resection of lipoma, mastectomy, pelvic adhesiolysis, hepatectomy, debridement of decubitus ulcer, pancreatectomy, hemorrhoids, splenectomy, pilodidal cyst removal and repair, thyroidectomy, debridement of statis ulcer, parathyroidectomy and biopsy.

4) Genihourinary Surgery/Urology, including:
superficial urinary bladder tumors, urethral and penile hemangioma, invasive bladder carcinoma, bladder neck obstructions, urethral strictures, holmium laser incision/excision/resection/ ablation, hemoastasis, vaporization, and enucleation in the treatment of benign prostatic hyperplasia (BPH), lesions of the external genitalia, bladder, urethral and ureteral tumors and condylomas 5) Gynecological Surgery during open and endoscopic procedures, including:
condyloma acuminate

6) Lithotripsy and Percutaneous Urinary Lithotripsy, including:
fragmentation of urinary calculi, fragmentation of kidney calculi, fragmentation of urethral calculi, treatment of distal impacted fragment of steinstrasse when guide wires cannot be passed

7) Orthopedic Surgery in pathological soft and cartilaginous tissue in small and large joints, including:
knee meniscectomy, ligament and tendon release, knee synovectomy, contouring and sculpting of articular surfaces, chondromalacia and tears, debridement of inflamed synovial tissue, loose body debridement, capsulectomy in the knee, lateral retinacular release, chondroplasty in the knee, debridement of the degenerative knee, chondromalacia ablation and plica removal

8) Otorhinolaryngology (ENT) Surgery in soft, mucosal, cartilaginous and bony tissue, including:
endosinus surgery, polypectomy, functional endoscopic sinus surgery, maxillary antrostomy, turbinate procedures (e.g.; turbinectomy), frontal sinusotomy, dacryocystorhinostomy (DCR), sphenoidotomy and ethmoidectomy

9) Percutaneous Cervical, Lumbar, and Thoracic Disc Decompression / Discectomy:
Superficial incision, excision, resection, ablation, coagulation, hemostasis and vaporization, with or without an endoscope, in the following:

-Percutaneous Lumbar Disc Decompression/Discectomy in soft, cartilaginous, and bony tissue, including:
foraminoplasty
-Percutaneous Cervical Disc Decompression/Discectomy in soft tissue, in patients with: uncomplicated ruptured or herniated discs, neck pain with radiation down the arm, symptoms and signs of sensory loss, tingling, numbness, muscle weakness, and/or decreased deep tendon reflexes, MRI, CT, myelogram, or discogram findings of disc herniation consistent with patient signs and symptoms, positive electromyography and/or nerve conduction studies, no improvement after 12 weeks of conservative therapy (i.e., physical therapy, traction, bed rest, exercises, and medication)
-Percutaneous Thoracic Disc Decompression/Discectomy in soft tissue, in patients with: uncomplicated ruptured or herniated discs, thoracic and intercostal intractable pain,

paresthesias at levels appropriate to the herniated discs visualized on MRI and CT-myelography, MRI, CT, myelogram, or discogram findings of disc herniation consistent with patient signs and symptoms, no improvement after 12 weeks of conservative therapy (i.e., physical therapy, traction, bed rest, exercises, and medication)

5. 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 Holinwon 30 and the predicate devices:

	Proposed Device	Predicate Device
K Number	K183563	K041660
Manufacturer	WON TECH Co., Ltd.	Trimedyne.Inc.
Model	Holinwon 30	OmniPulse Jr.™
Product Code	GEX	GEX
Intended Use/ Indications for Use	The Holinwon 30 Laser System is indicated for superficial incision, excision, resection, ablation, coagulation, hemostasis, and vaporization, with or without an endoscope, in multispecialty applications. *Refer to '4. Indications for use' above for more detail.	The OmniPulse Jr.™ Laser System is indicated for superficial incision, excision, resection, ablation, coagulation, hemostasis, and vaporization, with or without an endoscope, in multispecialty applications. *Same as '4. Indications for use' above.
Laser Type	Holmium:YAG laser	Holmium:YAG laser
Wavelength	2100 nm	2100 nm
Pulse Energy	0.1 - 3 J	0.2 – 3.5 J
Pulse Duration	600 microseconds ± 10%	350 microseconds
Repetition Rate	2 – 15 Hz	5 – 20 Hz
Output Power	0.2 – 30 W	1.4 – 30 W
Aiming Beam	Green, 532 nm ± 10%, less than 5 mW, Class 3R	Red, 3 mW maximum, Class 3R
Electrical consumption	230 VAC, 5.0 kVA(21 A), 50 Hz, single phase	230 VAC, 3.5 kVA, 15 A, 50/60 Hz, single phase
Dimensions(W x L x H)	37 cm× 71.4 cm× 89.4 cm	53 cm x 50 cm x 91 cm
Weight	70 kg	104 kg
Cooling	Self-contained air/water	Self-contained air/water

The key differences between Holinwon 30 and the predicate device are pulse duration and aiming beam, and which do not raise any new safety and effectiveness issues. The Holinwon 30 and predicate device have the same output power and pulse energy.

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Verification and validation activities were conducted to establish the performance and safety characteristics of the Holinwon 30. The results of these activities show that there are no any new safety and effectiveness issues. Therefore, the Holinwon 30 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	ANSI AAMI	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	Edition 3.1	2012
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	Edition 4	2014
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 3.1	2012
60825-1	IEC	Safety of Laser Products - Part 1: Equipment Classification, and Requirements	Edition 2	2007

2) Software Validation

The Holinwon 30 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

The optical fiber cable directly contacted with patient has got 510(k) clearance, K050738. According to the recommendations of ISO 10993-1 and FDA Blue Book Memo #G95-1, the following tests were performed for the certificate and clearance process:

-Cytotoxicity according to ISO 10993-5

-Intracutaneous reactivity according to ISO 10993-10
-Sensitization according to ISO 10993-10

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

No clinical studies were considered necessary and performed.

6. 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 WON TECH Co., Ltd., concludes that the Holinwon 30 is substantially equivalent in safety and effectiveness to the predicate device as described herein.