

K 123293

## Section 5 510(k) Summary

APR 11 2013

In accordance with 21 CFR 807.92 (Summary):

A summary of the information regarding the safety and effectiveness of the Pastelle Laser System, as required by the Safe Medical Device Amendments of 1990, is provided as follows:

### 510(k) Summary for the WON Technology Co., Ltd. Pastelle Q-Switched Nd:YAG Laser

1. **Applicant:** WON Technology Co., Ltd.
2. **Address:** WON Technology Co., Ltd.  
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Yuseong-gu, Daejeon  
Republic of Korea
3. **Contact Person:** Young-Seok Seo (The director of WON Technology Laboratory)
4. **Telephone:** +82-42-934-6800  
**Fax:** +82-42-934-9491  
**E-mail:** physys@wtlaser.com
5. **Preparation Date:** October 17, 2012
6. **Device Trade Name:** Pastelle
7. **Common Name:** Nd:YAG Laser
8. **Classification Name:** Laser Instrument, Surgical, Powered  
Product Code: GEX  
Panel: General & Plastic Surgery
9. **Legally Marketed Predicate Device:** Continuum-Electro Optics, Inc.  
MedLite C6 Q-Switched Nd:YAG Laser  
(K014234)

Lutronic Spectra VRMIII(K080248)  
HOYA Conbio RevLite Q-Switched Nd: YAG Laaser  
System (K083899)

**10. Description of the  
WON Technology  
Pastelle Q-Switched  
Nd:YAG Laser:**

The WON Technology's Pastelle Q-Switched Nd:YAG Laser uses a Nd:YAG material to generate the Q-switching laser. The device is comprised of a main body, articulated arm, foot switch and ancillary accessories.

This device is designed to provide laser energy for use in a variety of dermatological procedures. The 532nm and 1064nm wavelengths are absorbed by pigment and other chromophores within the skin to create the desired clinical effect.

The laser incorporates very broad laser pulses (6-20ns) designed to apply higher peak power over a very short period to minimize the time to absorb heat into the tissue.

**11. Intended use of the  
WON Technology Q-  
Switched Laser:**

WON Technology's Pastelle Q-Switched Nd:YAG Laser System is indicated for the Incision, Excision, Ablation and Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis.

**12. Performance Data:**

Bench studies indicate that the Pastelle device performs as intended. The following bench testing was performed: software validation, electrical safety, electromagnetic compatibility, transit testing and functional testing.

**13. Results of Clinical  
Study:**

No clinical studies were performed.

**\*Summary of Technological Characteristics:**

	<b>WON Technology Pastelle Q-Switched Nd:YAG Laser K123293</b>	<b>Continuum Electro- Optics, Inc. MedLite C6 Q-Switched Nd:YAG Laser K014234</b>
Laser Type	Q-Switched Nd:YAG	Q-Switched Nd:YAG
Wavelength	532nm,1064nm	532nm,1064nm
Pulse	Single,0-10Hz ±20%	Single,1, 2, 5 and 10Hz
Pulse duration	6 to 20ns	5 to 20ns
Power requirement	220V-230V AC, 50/60Hz	220V AC, 50/60Hz 110V AC, 50/60Hz
Spot size	2mm to 10mm Control value: 1mm	3, 4, 6, 8mm at 1064nm 2, 3, 4, 6mm at 532nm
Energy per pulse(MAX)	1300mJ at 1064nm 500mJ at 532nm	1000mJ at 1064nm 400mJ at 532nm

*H. O. S.*

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(Signature of Certifier)

Young-Seok Seo (Director of WON  
Technology Laboratory)

\_\_\_\_\_  
(Typed Name)

October 17, 2012

\_\_\_\_\_  
(Date)

K123293

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\*Pre-market Notification 510(k)

\*For a new submission, leave the 510(k) number blank.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-002

WON Technology Co., Ltd.  
% Northwest Clinical Research Group, Inc.  
Roberta Hines, President and CEO  
24125 8<sup>th</sup> Avenue Southeast  
Woodinville, Washington 98052

April 11, 2013

Re: K123293

Trade/Device Name: Pastelle Q-Switched Nd:YAG Laser  
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: March 05, 2013  
Received: March 18, 2013

Dear Ms. Hines:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours, FOR

**Peter D. Rumm -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indication for Use Statement**

510(k) Number (if known):     K123293    

Device Name: Trade Name, Pastelle

**Indications for Use**

WON Technology's Pastelle Q-Switched Nd:YAG Laser System is indicated for the Incision, Excision, Ablation and Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis.

Prescription Use     X      
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use                       
(Part 21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Neil R Ogden   
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Division Sign-Off for MXM  
Division of Surgical Devices  
Office of Device Evaluation  
510(k) Number: **K123293**