Section 5 510(k) Summary

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.

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3. Contact Person: Young-Seok Seo (The director of WON Technology Laboratory)

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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

MedLite C6 Q-Switched Nd:YAG Laser (K014234)
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:**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Laser Type</td>
<td>Q-Switched Nd:YAG</td>
<td>Q-Switched Nd:YAG</td>
</tr>
<tr>
<td>Wavelength</td>
<td>532nm, 1064nm</td>
<td>532nm, 1064nm</td>
</tr>
<tr>
<td>Pulse</td>
<td>Single, 0-10Hz ±20%</td>
<td>Single, 1, 2, 5 and 10Hz</td>
</tr>
<tr>
<td>Pulse duration</td>
<td>6 to 20ns</td>
<td>5 to 20ns</td>
</tr>
<tr>
<td>Power requirement</td>
<td>220V-230V AC, 50/60Hz</td>
<td>220V AC, 50/60Hz, 110V AC, 50/60Hz</td>
</tr>
<tr>
<td>Spot size</td>
<td>2mm to 10mm Control value: 1mm</td>
<td>3, 4, 6, 8mm at 1064nm, 2, 3, 4, 6mm at 532nm</td>
</tr>
<tr>
<td>Energy per pulse(MAX)</td>
<td>1300mJ at 1064nm, 500mJ at 532nm</td>
<td>1000mJ at 1064nm, 400mJ at 532nm</td>
</tr>
</tbody>
</table>

(Signature of Certifier)

Young-Seok Seo (Director of WON Technology Laboratory)

(Typed Name)

October 17, 2012

(Date)

K123293

*Pre-market Notification 510(k)*

*For a new submission, leave the 510(k) number blank.*
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" (21 CFR 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 AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden 2013.04.08 16:06:14 -04'00'
Division Sign-Off for MM
Division of Surgical Devices
Office of Device Evaluation
510(k) Number: K123293