August 28, 2026

Zhengzhou PZ Laser Slim Technology Co., Ltd.
Junmei Li
RA
3rd Floor, Bldg. 1, #101 Jinbai Rd., High-Tech Development Z
Zhengzhou, Henan 450001
China

Re: K261582
Trade/Device Name: Vacuum Roller RF Slimming Device for Medical Use (PZ-FY66-01, PZ-FY66-02)
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: NUV, ISA, PBX
Dated: May 12, 2026
Received: May 13, 2026

Dear Junmei Li:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.08.28 10:34:37 -04'00'

for 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)*
K261582

Device Name
Vacuum Roller RF Slimming Device for Medical Use (PZ-FY66-01, PZ-FY66-02)

Indications for Use *(Describe)*
The Vacuum Roller RF Slimming Device for Medical Use incorporates four therapeutic technologies: radiofrequency (RF), infrared (IR), vacuum, and mechanical roller massage. The device provides the following treatment modes:
• Mode 1 - Massage & IR Therapy: Vacuum + IR + Roller Massage
• Mode 2 - RF Massage Therapy: RF + Vacuum + Roller Massage
• Mode 3 - Vacuum/IR Body Contouring: Vacuum + IR
• Mode 4 - Massage Therapy: Vacuum + Roller Massage
• Mode 5 - IR Massage Therapy: IR + Roller Massage
The device is indicated for the following uses:
• Modes 1, 2, 5 are indicated for the temporary relief of minor muscle aches and pain.
• Modes 1, 2, 5 are indicated for the temporary relief of muscle spasm.
• Modes 1, 2, 5 are indicated for the temporary improvement of local blood circulation.
• Modes 1, 2, 3, 4 are indicated for the temporary reduction in the appearance of cellulite.
• Modes 1, 3, 5 are indicated for the temporary reduction of thigh circumference.

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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# 510(k Summary K261582

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K261582

**1 Date of Preparation**

08/26/2026

**2 Sponsor**

Zhengzhou PZ Laser Slim Technology Co., Ltd.

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**3 Submission Correspondent**

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Tel: +86-18403935976

Email: 1055078817@qq.com

**4 Identification of Subject Device**

Trade Name: Vacuum Roller RF Slimming Device for Medical Use (PZ-FY66-01, PZ-FY66-02)

Common Name: Massager, Vacuum, Light induced heating

Model(s): PZ-FY66-01, PZ-FY66-02

Regulatory Information:

Classification Name: Massager, Vacuum, Light induced heating

Classification: II

Product Code: NUV, ISA,PBX

Regulation Number: 21 CFR 878.4810

Review Panel: Physical Medicine, General & Plastic Surgery

Intended Use:

The Vacuum Roller RF Slimming Device for Medical Use is indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences.

Indication for Use:

“The Vacuum Roller RF Slimming Device for Medical Use incorporates four therapeutic technologies: radiofrequency (RF), infrared (IR), vacuum, and mechanical roller massage. The device provides the following treatment modes:

• Mode 1 - Massage & IR Therapy: Vacuum + IR + Roller Massage

• Mode 2 - RF Massage Therapy: RF + Vacuum + Roller Massage

• Mode 3 - Vacuum/IR Body Contouring: Vacuum + IR

• Mode 4 - Massage Therapy: Vacuum + Roller Massage

• Mode 5 - IR Massage Therapy: IR + Roller Massage

The device is indicated for the following uses:

• Modes 1, 2, 5 are indicated for the temporary relief of minor muscle aches and pain.

• Modes 1, 2, 5 are indicated for the temporary relief of muscle spasm.

• Modes 1, 2, 5 are indicated for the temporary improvement of local blood circulation.

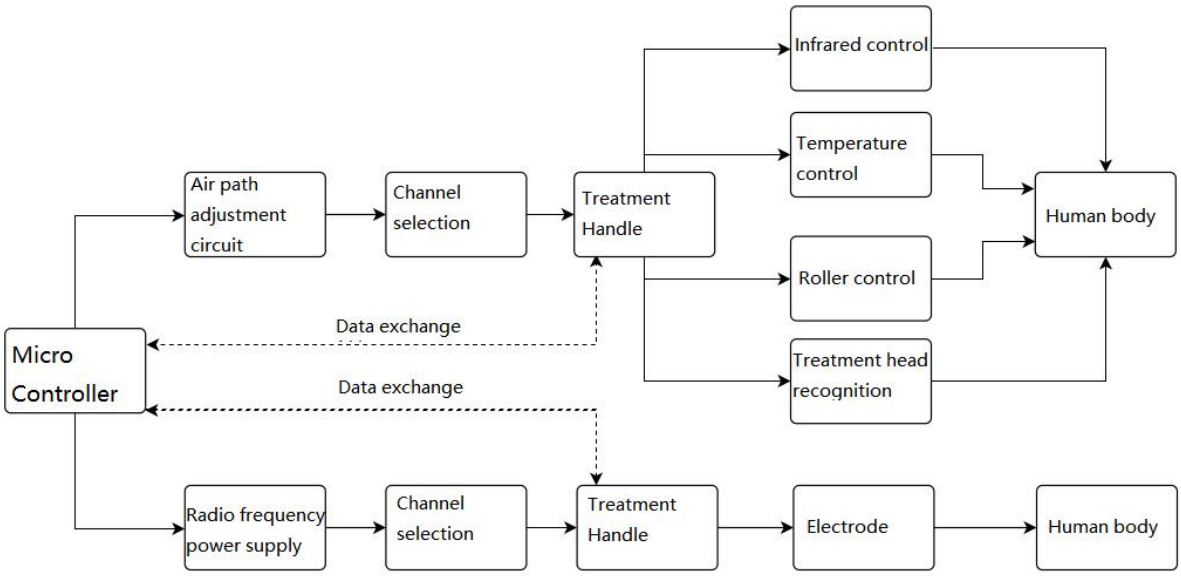
• Modes 1, 2, 3, 4 are indicated for the temporary reduction in the appearance of cellulite.

• Modes 1, 3, 5 are indicated for the temporary reduction of thigh circumference.”

**5 Device Description**

The Vacuum Roller RF Slimming Device for Medical Use controls the RF power supply through the micro controller. After the channel is selected, the electrode is controlled by the treatment handle. Finally, it is applied to the human body. And data is exchanged between the micro controller and the treatment handle.

The micro controller controls the gas path adjustment circuit. After the channel selection, infrared control, temperature control, roller control and treatment head recognition are completed through the treatment handle. Finally, it is applied to the human body. And data is exchanged between the micro controller and the treatment handle.




The system principle block is shown in Fig. 5-1.

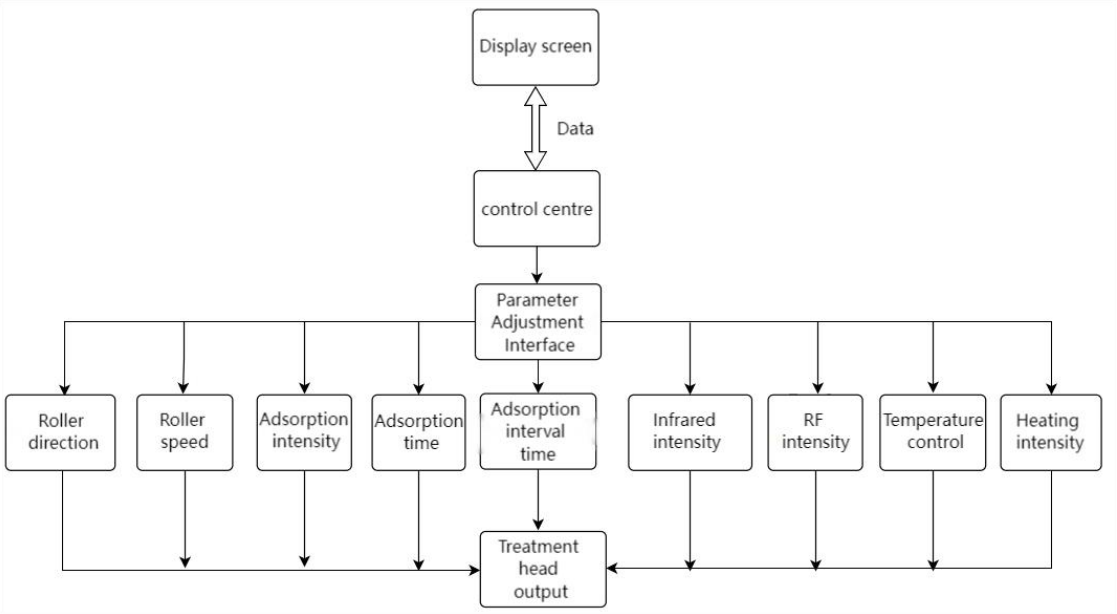



Fig. 5-1 System principle block

The model of the Vacuum Roller RF Slimming Device for Medical Use: PZ-FY66-01, PZ-FY66-02

The subject device includes the following components:

Table 5-1 Main Components of Subject Device

| Components | | Function Description |
|---|---|---|
| Host | Power supply | 100-240V~ 50/60Hz |

| | | |
|---|---|---|
| | switching power supply | Convert the input voltage into the required output voltage to meet the needs of different electronic devices. |
| | display screen | For human and machine interaction. |
| Power cord | | A connection tool that transfers electricity from a power source to an electrical device, allowing the device to function properly. |
| Treatment handle | | Connect the host and the treatment head to realize the infrared control, temperature control, roller control and treatment head recognition function. |
| Treatment head | | The electrical signal is converted into electrical energy to act on the patient. |
| Pendant | | Suspended treatment handle. |
| Socket | | Connect the main unit and treatment handle. |
| Caster | | Installed at the bottom of the device to increase the mobility and flexibility of the device. |
| Main unit | | Main unit includes RF power supply, switching power supply, control board and display screen. The switching power supply can convert the input voltage into the required output voltage to meet the needs of different electronic devices. |
| Key switch | | Turn the device on/off. |
| EMG stop switch | | Emergency stop device operation. |
| Fuse | | Overload protection. |
| Power input sock | | Connector for connecting the power cord to the device |
| Filter | | Remove unwanted frequency components from a signal while retaining the desired frequency components. |

| | |
|---|---|
| DC contactor | Connect or disconnect the DC main circuit with load. |

**6 Identification of Predicate Device**

Predicate Device1

510(k) Number: K161892

Product Name: Slimming Treatment Device

Manufacturer: Beijing Honkon Technologies Co., Ltd

Predicate Device 2

510(k) Number: K122579

Product Name: VelaShape

Manufacturer: Syneron Medical, Limited

**7 Non-Clinical Test Conclusion**

Non-clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

IEC 60601-1:2005+A1:2012+A2:2020,Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;

IEC 60601-1-2:2014+A1:2020, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests;

IEC 60601-2-2 : 2017+A1:2023Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

IEC 62304:2015 , Medical device software – Software life cycle processes;

ISO 14971:2019 , Medical devices – Application of risk management to medical devices;

ISO 10993-1:2020, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;

ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity;

ISO 10993-10:2021, Biological Evaluation of Medical Device, Part 10-Test for irritation and skin sensitization;

ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation;

**8 Clinical Test Conclusion**

No clinical study is included in this submission.

**9 Substantially Equivalent (SE) Comparison**

Table 9-1 General Comparison

| **Items** | **Subject Device**<br>**K261582** | **Predicate Device 1:**<br>**K161892** | **Predicate Device 2:**<br>**K122579** | **Analysis** |
|---|---|---|---|---|
| Manufacturer | Zhengzhou PZ Laser Slim Technology Co., Ltd. | Beijing Honkon Technologies Co., Ltd | Syneron Medical, Limited | N/A |
| Regulation numbers | 21 CFR 878.4810 | 21 CFR 878.4810 | 21 CFR 878.4810 | Same |
| Product Code | PBX, NUV, ISA | NUV, ISA | NUV | Analysis 1 |
| Regulatory Class | Class II | Class II | Class II | Same |
| Clinical Use | Prescription use | Prescription use | Prescription use | Same |
| Intended use<br><br>Indication For Use | The Vacuum Roller RF Slimming Device for Medical Use is indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences.<br>"The Vacuum Roller RF Slimming Device for Medical Use incorporates four therapeutic technologies: | The HONKON-Slimming I+/HONKON-Slimming III+ are indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences. | The VelaShape is indicated for the relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation, temporary reduction in the appearance of cellulite, and for temporary reduction of thighs circumferences. | Same |

| | | | | |
|---|---|---|---|---|
| | radiofrequency (RF), infrared (IR), vacuum, and mechanical roller massage. The device provides the following treatment modes:<br>• Mode 1 - Massage & IR Therapy: Vacuum + IR + Roller Massage<br>• Mode 2 - RF Massage Therapy: RF + Vacuum + Roller Massage<br>• Mode 3 - Vacuum/IR Body Contouring: Vacuum + IR<br>• Mode 4 - Massage Therapy: Vacuum + Roller Massage<br>• Mode 5 - IR Massage Therapy: IR + Roller Massage<br>The device is indicated for the following uses:<br>• Modes 1, 2, 5 are indicated for the temporary relief of minor muscle aches and pain.<br>• Modes 1, 2, 5 are indicated for the temporary relief of muscle spasm.<br>• Modes 1, 2, 5 are indicated for the temporary improvement of local blood circulation.<br>• Modes 1, 2, 3, 4 are indicated for the temporary reduction in the appearance of cellulite.<br>• Modes 1, 3, 5 are indicated for the temporary reduction of thigh circumference.” | | | |
| Target Population | Adult Population which requires treatment as specified in the indication for | Adult Population which requires treatment as specified in the | Adult Population which requires treatment as specified in the indication | Same |

| | | | | |
|---|---|---|---|---|
| | use | indication for use | for use | |
| Anatomical Sites | Body parts requiring treatment as specified in the indication for use | Body parts requiring treatment as specified in the indication for use | Body parts requiring treatment as specified in the indication for use | Same |

Analysis 1:

Although the product code for the predicate device is not explicitly listed as including "PBX" in its publicly available 510(k) Summary, the predicate device actually incorporates the designs and functions associated with that code - specifically PBX (Massager, Vacuum, Radiofrequency-Induced Heat). Therefore, the subject device and the predicate device are equivalent in terms of technological characteristics and intended functionality. This difference will not affect the safety and efficacy of the subject device.

Table 9-2 Performance Comparison

| Items | Subject Device: K261582 | Predicate device 1: K161892 | Predicate Device 2 : K122579 | Analysis |
|---|---|---|---|---|
| RF Output Energy | Up to 220W | 40-400W | Up to 150W | Analysis 1 |
| RF Output Frequency | 1MHz | 1MHz | N.A | Same |
| Max. RF output energy density | Large treatment head: 6.41W/cm²<br>Adsorption treatment head: 10.01W/cm²<br>Radio frequency treatment head: 9.29W/cm² | XF-I+: 12.14W/cm²<br>XF-VII+: 27W/cm² | 115.38W/cm²<br>6.67W/cm²<br>12 W/cm²<br>9.38W/cm² | Analysis 2 |
| Infrared energy | Large treatment handle: Max. 6W<br>Medium treatment handle: Max. 4W | XF-I+ & XF-VII+:<br>I: 5W II : 7W III : 8W IV : 9W V : 10W | Up to 3.3W | Analysis 3 |
| Infrared wavelengths | 850nm | 700-2000nm | 850nm | Analysis 4 |
| Max. IR output energy density | Large treatment handle: 0.17W/cm²<br>Adsorption treatment head: 0.18W/cm²<br>Radio frequency treatment head: 0.63W/cm² | XF-I+: 0.30W/cm²<br>XF-VII+: 0.67W/cm² | 2.54W/cm²<br>0.44W/cm²<br>0.26W/cm²<br>0.21W/cm² | Analysis 5 |
| Vacuum | Pulsed<br>(Max.-80Kpa(-0.08Mpa)) | Pulsed<br>(-0.08Mpa —<br>-0.01Mpa) | Pulsed | Analysis 6 |
| Mechanical Massage | Yes | Yes | N.A. | Same |
| Treatment Area | Large treatment head: 3433mm² | XF-I+: 3294 mm² | VContour Applicator: Small Cover<br>Medium Cover | Analysis 7 |

| | | | | |
|---|---|---|---|---|
| | Adsorption head: 2198mm²<br>Radio frequency treatment head: 634mm²<br>Rollerball treatment handle: 32448mm² | XF-VII+: 1482mm² | Large Cover:<br>130 mm²<br>750 mm²<br>1250 mm²<br>VSmooth Applicator:<br>1600 mm² | |
| Weight | 60KG | 48KG | 20kg / 44lbs | Analysis 8 |
| Size (mm) L*W*H | 809mm*809mm*1392mm | 434mm * 531mm *1354mm<br>(Slimming I+)<br>531mm * 441mm *1716mm<br>(Slimming III+) | 380* 490 *1320 | Analysis 9 |
| Power supply | AC100V-240V; 50Hz/60Hz | 110V, 60HZ | 110VAC; 50Hz; | Analysis 10 |
| Patient Contact Material | Handpiece<br>Suction roller | Handpiece<br>Suction roller | Handpiece<br>Suction roller | Same |

**Analysis 1:**

Compared with predicate device, although there is a difference but the reasons are as follows. Although there are differences in the "RF output energy" between the subject device and the predicate device, it was all tested and is compliant with IEC 60601-2-2. And the High "RF output energy" within the range of the predicate device's.

Therefore the difference doesn't impact essential performance, basic safety or substantial equivalence.

**Analysis 2:**

Compared with predicate device, although there is a difference but the reasons are as follows. Although there are differences in the "Max. RF output energy density" between the subject device and the predicate device. And the "Max. RF output energy density" within the range of the predicate device's. Therefore the difference doesn't impact essential performance, basic safety or substantial equivalence.

**Analysis 3:**

Compared with predicate device, although there is a difference but the reasons are as follows. Although there are differences in the "Infrared energy" between the subject

device and the predicate device. And the "Infrared energy" within the range of the predicate device's. Therefore the difference doesn't impact essential performance, basic safety or substantial equivalence.

**Analysis 4:**

Compared with predicate device, although there is a difference but the reasons are as follows. Although the "Infrared wavelengths" of the subject device is different than in the predicate device, the "Infrared wavelengths" within the range of the predicate device's. Therefore the difference doesn't impact essential performance, basic safety or substantial equivalence.

**Analysis 5:**

The subject device maximum IR output energy density ranges from a lower limit of 0.17 W/cm² to an upper limit of 0.63 W/cm². The upper limit of the subject device (0.63 W/cm²) falls within the range of the predicate device's upper limit, while the lower limit (0.17 W/cm²) is similar to that of predicate device 2 (0.21 W/cm²); the slight difference of 0.04 W/cm² falls within the margin of error(±20%) and does not impact the safety or effectiveness of the subject device. Therefore, the difference in maximum IR output energy density does not affect the safety or effectiveness of the subject device.

**Analysis 6:**

Compared with predicate device, although there is a difference but the reasons are as follows. Although the "Vacuum" of the subject device is different than in the predicate device, the high "Vacuum" within the range of the predicate device's.

Therefore the difference doesn't impact essential performance, basic safety or substantial equivalence.

**Analysis 7:**

The lower and upper limits for the IR Treatment Area of the subject device are 634mm² and 3433mm², respectively.The upper limit of the subject device (3433 mm²) is similar to that of predicate device 1, and the lower limit (634 mm²) falls within the range of predicate device 2. Therefore, the differences in IR Treatment Area do not affect the safety and effectiveness of the subject device.

**Analysis 8:**

Not identical. That difference does not generate a safety and effectiveness issue.

**Analysis 9:**

Not identical. That difference does not generate a safety and effectiveness issue.

**Analysis 10:**

Not identical. The subject device provides a different “Power supply” than the predicate device. Electrical safety testing and EMC testing have been performed for the subject device. Risk analysis have also been performed to support proof of safety

and effectiveness of the subject device. This difference does not raise new questions of safety and effectiveness compared to the predicate devices.

Table 9-3 Safety Comparison

| Item | Subject Device | Predicate Device1,2 | Remark |
|---|---|---|---|
| Electrical Safety | Comply with IEC 60601-1 | Comply with IEC 60601-1 | SE |
| EMC | Comply with IEC 60601-1-2 | Comply with IEC 60601-1-2 | SE |
| | Comply with IEC TS 60601-4-2 | / | |
| RF Safety | Comply with IEC 60601-2-2 | Comply with IEC 60601-2-2 | SE |
| Biocompatibility | No toxicity<br>(ISO 10993-5) | Cytotoxicity<br>No toxicity<br>(ISO 10993-5) | SE |
| | Applied sample did not<br>induce irritation to skin.<br>(ISO 10993-10) | Irritation<br>Applied sample did not induce irritation to skin.<br>(ISO 10993-10) | SE |
| | The test article showed no signification evidence of causing skin sensitization in the New Zealand white rabbits.<br>(ISO 10993-23) | Sensitization<br>The test article showed no signification evidence of causing skin<br>sensitization in the guinea pig.<br>(ISO 10993-10) | SE |

Analysis

The subject device is substantially equivalent to the predicate devices. Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.

**10 Substantially Equivalency Conclusion**

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate devices K161892 and K122579.