June 8, 2020

Shenzhen Dongjilian Electronics Co., Ltd.
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.
Room 2012#, Gebu commercial building, Hongxing community,
Songgang street
Shenzhen, 518105 Cn

Re: K193354
Trade/Device Name: Air Compression Therapy Device
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: May 28, 2020
Received: June 8, 2020

Dear Reanny Wang:

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,

Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K193354

Device Name
Air Compression Therapy Device

Indications for Use *(Describe)*
The Air Compression Therapy Device is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment.

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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# Traditional 510(k) Summary

# K193354

## 1. Information of Submitter and Correspondent

### Submitter's information:


**Company Name:** Shenzhen Dongjilian Electronics Co.,Ltd.

**Street Address:** B1/1-5F, Tonglu Industrial Area, 70# Tongxin Road, Tongxin Community, Longgang District

**City:** Shenzhen

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**Telephone:** +86(755) 89964118

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**Contact Person:** ZHANG HONG

**Contact Title:** General Manager

**Contact Email:** zh@dongjilian.com


**Date Prepared:** May 27, 2020

### Submission correspondent's information:


Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

Address: Room 2012#, Gebu commercial building, Hongxing community, Songgang street, Baoan district, Shenzhen 518000, China

Contact Person: Reanny Wang

E-mail: reanny@reanny.com

## 2. Device Information

**Trade Name:** Air Compression Therapy Device

**Model:** S9019

**Common Name:** Powered Inflatable Tube Massager

**Classification Name:** Massager, Powered Inflatable Tube

**Regulation:** 21 CFR § 890.5650

**Device Class:** Class 2

**Product Code:** IRP

## 3. Identification of Predicate Device(s)

| | | | |
|---|---|---|---|
| **Manufacturer** | Rapid Reboot Recovery Products, LLC | Salton,INC | NormaTec Industries, LP |
| **Legally Marketed Device** | Rapid Reboot Compression Therapy System | Relaxor Perfect Touch Air Massaging System | NormaTec Pulse and NormaTec Pulse Pro |
| **510(K) Number** | K182668 | K030437 | K160608 |

## 4. Description of Device

Air Compression Therapy Device consists of an air pump, air pressure sensor, and sleeves working together as one unit. The air pump is connected to the dedicated sleeves via a series of hoses; each sleeve has 3 compression chambers. The compression massage direction is from foot to thigh. By inflating the air chambers sequentially and then deflating as one cycle, the pressure can be adjusted to avoid any discomfort to the patient. The sleeve works under the action of sensor and microprocessor. Software controls the timing and pressure reflected by the sensor, cycling airflow into and out of the sleeves to compress body.

## 5. Indications for Use

The Air Compression Therapy Device is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment.

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## 6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

### 6.1 Non-clinical testing

A series of safety and performance tests were conducted on the subject device.

- Product service life
- Software validation
- Electromagnetic compatibility and electrical safety
- Function test

All the test results demonstrate Air Compression Therapy Device meets the requirements of its pre-defined acceptance criteria and intended use, and it is substantially equivalent to the predicate devices.

### 6.2 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

## 7. Performance Summary

The devices conform to applicable standards as follow table:

| Test Type | Standard Designation Number | FDA Recognition Status | Outcome for Device |
|---|---|---|---|
| Safety | ES 60601-1:2005+ A1:2012 | Yes | Conforms |
| EMC | IEC 60601-1-2:2014 | Yes | Conforms |
| Home healthcare environment | IEC 60601-1-11:2015 | Yes | Conforms |

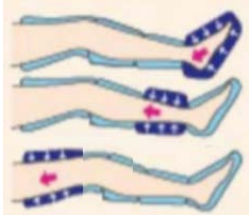
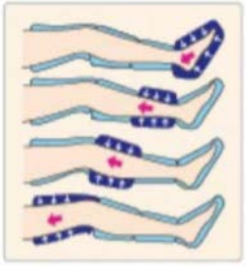
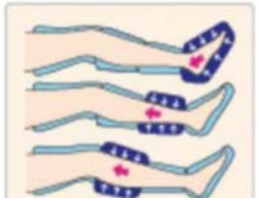
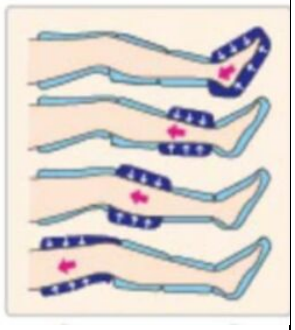
| | | | |
|---|---|---|---|
| Performance | Enterprise standard | Yes | Conforms |
| Biocompatibility | ISO 10993-10:2010；<br>ISO 10993-5:2009 | Yes | Conforms |
| Software | IEC 62304:2006/A1:2016 | Yes | Conforms |
| Usability | IEC 60601-1-6:<br>2010+A1:2013<br>IEC 62366-1:2015 | Yes | Conforms |
| Risk management | ISO 14971:2007 | Yes | Conforms |

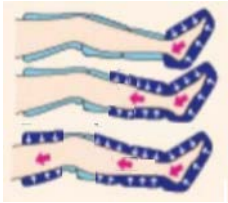
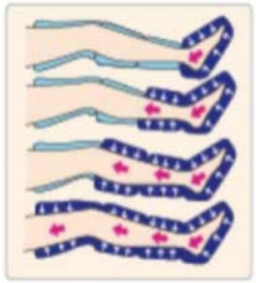
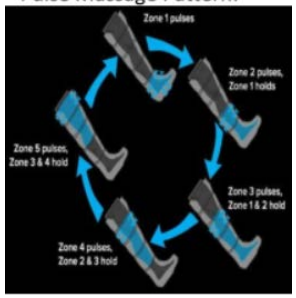
## 8. Discussion of Comparison to Predicate Devices.

The Air Compression Therapy Device submitted in this 510(k) submission is substantially equivalent in intended use, technological characteristics/ principles of operation, materials, and performance to the cleared Rapid Reboot Compression Therapy System **K182668**, Relaxor Perfect Touch Air Massaging System **K030437**, and NormaTec Pulse and NormaTec Pulse Pro **K160608**. Differences between the subject and predicate devices do not raise new questions of safety and effectiveness.

| Device | Subject device | Primary Predicate device | Secondary Predicate device | Third Predicate device | Comparison |
|---|---|---|---|---|---|
| Manufacturer | Shenzhen Dongjilian Electronics Co.,Ltd. | Rapid Reboot Recovery Products, LLC | Salton,Inc | NormaTec Industries, LP | NA |
| 510(K) number | K193354 | K182668 | K030437 | K160608 | NA |
| Model name | S9019 | Rapid Reboot Compression Therapy System | Relaxor Perfect Touch Air Massaging System | NormaTec Pulse and NormaTec Pulse Pro | NA |
| Classification | Class II Device, IRP (21 CFR890.5650) | Class II Device, IRP (21 CFR890.5650) | Class II Device, IRP (21 CFR890.5650) | Class II Device, IRP (21 CFR890.5650) | Same |
| Indications for Use (IFU) | The Air Compression Therapy Device is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment. | The Rapid Reboot Compression Therapy System is indicated for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. The Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues by using an inflatable garment. | The Perfect Touch Air Massaging System is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Perfect Touch simulates kneading and stroking of tissues by using an inflatable garment. | The NormaTec Pulse and Pulse Pro is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. | Same |
| Treatment area/Structure of Sleeves | Low limbs (Foot, calf and upper leg) | Leg (including of foot, calf, knee, upper leg);<br>Hip (including of upper legs, glutes, hips, lower back);<br>Arm (including of entire arm, shoulder, upper chest and back) | Leg (including of foot, calf);<br>Back (including of lower and mid back);<br>Arm (including of forearm, lower bicep) | Leg (including of foot, calf, knee, upper leg);<br>Hip (including of upper legs, glutes, hips, lower back);<br>Arm (including of entire arm, shoulder, | Same |

| Device | Subject device | Primary Predicate device | Secondary Predicate device | Third Predicate device | Comparison |
|---|---|---|---|---|---|
| | | | | upper chest and back). | |
| OTC or Rx | OTC | OTC | OTC | OTC | Same |
| Environment of Use: | Clinics, hospital, athlete training, and home environments | Clinics, hospital, athlete training, and home environments | Home environment | Clinics, hospital, athlete training, and home environments | Same |
| Power source | 100~240V 50/60Hz | 110V，60HZ | 120V, 60Hz | 100- 240 VAC input | Same |
| Power Consumption | 12W | 30W | 26W | 14W | Similar *Note 3* |
| SW/Firmware/ Microprocessor Control | Microprocessor | Microprocessor | Microprocessor | Microprocessor | Same |
| Therapy Time | 20 minutes | User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time. | 15 minutes | User controlled 10 minutes to 175 minutes or continuous –total time over 4 segments | Similar *Note 1* |
| Output pressure range | 0~240 mmHg | 0~200 mmHg | 80 to 250 mmHg | 30-110 mmHg | Similar *Note 2* |
| Air pressure level /Compression levels | 3 levels settings: low level:150mmHg; Mid level:185mmHg； High Level: 215mmHg | Not publicly available | Not publicly available | Not publicly available | |
| Pressure error range | ±25mmHg | Not publicly available | Not publicly available | Unknown | |
| Inflation time | 3-30s | Not publicly available | Not publicly available | Not publicly available | Similar *Note 11* |
| Keep time | 1-5s | Not publicly available | Not publicly available | Not publicly available | |
| Deflation time | 1-5s | Not publicly available | Not publicly available | Not publicly available | |
| Mode types | Sequential/ Peristaltic | Sequential/ Peristaltic | Sequential/ Peristaltic | Sequential/ Peristaltic | Same |
| Cycle time | Range of 25 sec to 3 | Not publicly available | Not publicly available | Not publicly available | Similar |

| Device | Subject device | Primary Predicate device | Secondary Predicate device | Third Predicate device | Comparison |
|---|---|---|---|---|---|
| | min 40 sec | | | | *Note 4* |
| Number of chambers | 3 Chambers | 4 Chambers | 12 Chambers | 4 Chambers | Similar<br>*Note 7* |
| Number of treatment mode | 3 modes | 2 modes | 1 mode | 2 modes | Similar<br>*Note 6* |
| Modes (visual description) | **Mode 1**:<br>Starting with the foot chamber and progressing up the thigh chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. Once the thigh section decompresses, the cycle begins again.<br>Mode 1 follows this pressure sequence:<br>  <br>**Mode 2:**<br>Starting with the foot chamber and progressing up the thigh, each section | **Mode A:**<br>Starting with the distal chamber and progressing up the proximal chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. Once the top section decompresses, the cycle begins again.<br>Mode A follows this pressure sequence:<br>  <br>**Mode B:**<br>Starting with the distal | Starting with the distal chamber and progressing up the proximal chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. Operating until the top section decompresses, the cycle begins again.<br>Only has one mode. Follows this sequence:<br>  | **Sequential mode:**<br>Starting with the distal chamber and progressing up the proximal chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. Once the top section decompresses, the cycle begins again. again.<br>"Sequential:"<br>  <br>**Normatec Pulse** | Same |

| Device | Subject device | Primary Predicate device | Secondary Predicate device | Third Predicate device | Comparison |
|---|---|---|---|---|---|
| | compresses and the pressure gradually rises to the pre-determined air pressure level, holds the air until the entire garment is compressed. All three sections then decompress simultaneously and the air pressure drops, then cycle begins again. Mode 2 follows this pressure sequence:<br>  <br>**Mode 3:**<br>include two stage, stage 1: it work according to the method of mode 1, after the stage 1 is completed, it go to stage 2(working according to the method of mode 2) without interruption time until finish the stage 2, then enter next cycle without interruption .<br>Mode1 ⇄ Mode2<br>The pressure sequence | chamber and progressing up the proximal chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, holds the air until the entire boot is compressed. All four sections then decompress simultaneously and the air pressure drops, then cycle begins again.<br><br>Mode B follows this pressure sequence:<br>  | | **mode:**<br>Starting with the distal zone and progressing up the proximal zone, one zone compresses and the pressure gradually rises to the pre-determined air pressure level, holds the air of previous two zone , the other zones do not hold, until the last zone finished, deflate the all last three zone then enter into next cycle.<br>"Pulse Massage Pattern:"<br>  | |

| Device | Subject device | Primary Predicate device | Secondary Predicate device | Third Predicate device | Comparison |
|---|---|---|---|---|---|
| | of mode 3 combines mode 1 and mode 2 | | | | |
| Noise level | ≤ 65dB | Not publicly available | Not publicly available | Not publicly available | Similar<br>*Note 9* |
| Sleeve Material | Nylon with a Polyurethane laminate | Nylon with a Polyurethane laminate | Nylon with a Polyurethane laminate | Nylon with a polyurethane laminate | Same |
| Housing Materials | Molded ABS enclosure | Molded ABS enclosure | Molded ABS enclosure | Molded ABS enclosure | Same |
| Patient contact | Non-conductive attachments | Non-conductive attachments | Non-conductive attachments | Non-conductive attachments | Same |
| Size and appearance | 10.2×5.9×25.6（in）<br>  | 10” x 6.5” x 5”<br>  | 9” x 6” x 6”<br>  | 4” x 5” x 9”<br>  | Different<br>*Note 5* |
| Weight | 4.6 pounds | 5.8 pounds | 3.2 pounds | 3.6 pounds | |
| Size and appearance of sleeves (leg part) | Leg:<br>  | Leg:<br>  | Leg:<br>  <br>One size: 10” x 22” | Leg:<br>  <br>Short: 14” x 43”<br>Standard: 14” x 48”<br>Tall: 14” x 60” | Similar<br>*Note 8* |

| Device | Subject device | Primary Predicate device | Secondary Predicate device | Third Predicate device | Comparison |
|---|---|---|---|---|---|
| | One size：73*26cm | X-Short: 14" x 41"<br>Short: 14" x 43"<br>Medium: 14" x 45"<br>Long: 14" x 48"<br>X-Long: 14" x 52" | | | |
| Safety Features | Standby button allows user to stop therapy session at any time | Button on display allows user to stop or pause therapy session at any time. | Button on display allows user to stop or pause therapy session at any time | Button on display allows user to stop or pause therapy session at any time. | Same |
| Operating environment | Temperature: 5℃-40℃, Humidity:5%-90% non-condensing | Not publicly available | Not publicly available | Not publicly available | Similar<br>*Note 10* |
| Transportation & Storage environment | Temperature: -20℃~55℃; Humidity:5%-90% non-condensing Atmospheric Pressure:75kPa-106kPa | Not publicly available | Not publicly available | Not publicly available | |
| Standards | ES 60601-1; IEC60601-1-2; ISO 10993-5: ISO 10993-10; IEC 60601-1-11 | IEC 60601-1; IEC60601-1-2; ISO 10993-5: ISO 10993-10 | Not available | IEC 60601-1; IEC 60601-1-2; ISO 10993-5; ISO 10993-10; IEC 60601-1-11 | Same |

## Similarity and Difference

The Air Compression Therapy Device S9019 has been compared with Rapid Reboot Compression Therapy System (K182668), Relaxor Perfect Touch Air Massaging System (K030437) and NormaTec Pulse and NormaTec Pulse Pro (K160608). The subject device has same intended use and principle of operation, similar technological characteristics as that of predicate devices. Although there are several specifications that are different between the subject device and predicate devices, the comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore, the difference between the subject device and the predicate devices do not raise any problem of substantial equivalence. The subject devices is substantially equivalent to the predicate devices in safety and performance claims.

***Note 1:*** Although the treatment time of subject device is different the predicate device, but the treatment time of subject device was within the range of predicated device, so the small differences do not affect the safety and effectiveness.

***Note 2:*** Although the “Output pressure range” of the subject device is different from that of the predicate devices, but the minimum air pressure (0mmHg) of subject device is the same as the predicate device 1, the maximum air pressure of subject device (240mmHg) is within the output pressure range of the predicate device 2 (80 to 250 mmHg), in general, the output pressure range of subject device is within the range of those predicate devices. Additionally, the subject device was conforms to ANSI/AAMI ES60601-1 and ISO 14971, so the small differences do not affect the safety and effectiveness. Although the “air pressure level /compression levels” of subject device is different to the predicate devices, but they output air pressure range are similar, so the pressure level different do not affect the safety and effectiveness. Although we don’t know the pressure error of predicated device, but due to their “output pressure range” are similar, so this item does not affect the safety and effectiveness.

***Note 3:*** Although the “power consumption” of the subject device is different than the predicate devices, they both use a power adaptor and the adaptor both comply with ANSI/AAMI ES60601-1, so the difference does not affect the safety and effectiveness.

***Note 4:*** Although the “Cycle time” of subject device is different the predicate devices, but the range of cycle time was between the predicate 3 (maximum value) and predicate device 2 (minimum value), so the small difference do not affect the safety and effectiveness.

***Note 5:*** Although the “Size and appearance” and “Weight” between the predicate devices and subject device are different, they are both complied with ANSI/AAMI ES60601-1 and IEC 60601-1-2, so the differences do not affect the safety and effectiveness.

***Note 6:*** Although the “Number of treatment mode” is different the predicate device, the “Indications for Use”, “Principles of operations” and “Modes (visual description)” are same, so these differences do not affect the safety and effectiveness.

***Note 7:*** Although the “Number of chambers” of subject device is different to the predicated device,

but due to the chamber number only determines the applicable treatment site, while the “applicable treatment site” and “Indications for Use” of subject device is within the range of predicated device, so the differences do not affect the safety and effectiveness.

***Note 8:*** The “Size and appearance of sleeves (leg part)” of subject device is different the predicate device, because their chamber number and applicable treatment site is different. Based the analysis as the NOTE 7, we know: although the “Size and appearance of sleeves (leg part)” between the predicate devices and subject device is different, but the “applicable treatment site” and “Indications for Use” of subject device is within the range of predicated device, so the differences do not affect the safety and effectiveness.

***Note 9:*** Although the “Noise level” of predicate devices are unknown, but there are both had passed the ANSI/AAMI ES60601-1 and ISO 14971 standards, so the difference do not affect safety or effectiveness issue.

***Note 10:*** Although the “Operating environment” and “Transportation & Storage environment” of subject devices are different to the predicate devices, but they are both compliance with the ANSI/AAMI ES60601-1 and IEC 60601-1-11 standards, so the small difference will not affect the safety or effectiveness issue.

***Note 11:*** Although the predicate device does not disclosure the inflation/ keep/ deflation time, it is not possible to directly determine the substantially equivalent between the subject device and predicate device. For the safety: the subject device has compliance with IEC 60601-1 and ISO 14971 standards. And the subject device has designed the pressure sensor to protection the over-pressure, so the subject device was safety. For the effectiveness: since the treatment mode, treatment pressure and cycle time of the subject device is similar to the predicate devices, so we can be considered that the subject device and predicate device had similar effectiveness. Based on the above analysis, can be considered the small difference will not affect the safety or effectiveness issue.

## 9. Conclusions

The subject device has same intended use, principle of operation, and technological characteristics as the predicate devices. Although there are several specifications that are different between these devices, testing and discussion been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results conformed with the test requests. Therefore, the differences between the subject device and the predicate devices do not raise any concerns with respect to substantial equivalence. The subject device is substantially equivalent to the predicate devices and the differences in technological characteristics do not raise different questions of safety and effectiveness based on the testing submitted to support this submission.