October 26, 2023

Jiangsu MaxF Electric Appliance Co., Ltd
% Cassie Lee
Official Correspondent
Share Info (Guangzhou) Medical Consultant Ltd
No. 1919-1920, Building D3, Minjie Plaza
Shuixi Road, Huangpu District
Guangzhou, Guangdong 510000
China

Re: K230500
Trade/Device Name: Air Compression Therapy Recovery System (model: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601, MF-AWI.LED.A-601, MF-AWI.LED.B-601, MF-AWI.OLED.A-401, MF-AWI.LED.A-401, MF-AWI.LED.B-401)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: August 10, 2023
Received: August 11, 2023

Dear Cassie Lee:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Heather L. Dean -S

Heather Dean, PhD

Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Rehabilitation 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230500

Device Name
Air Compression Therapy Recovery System (model: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601, MF-AWI.LED.A-601, MF-AWI.LED.B-601, MF-AWI.OLED.A-401, MF-AWI.LED.A-401, MF-AWI.LED.B-401)

Indications for Use *(Describe)*
The Air Compression Therapy Recovery System (model: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601, MF-AWI.LED.A-601, MF-AWI.LED.B-601, MF-AWI.OLED.A-401, MF-AWI.LED.A-401, MF-AWI.LED.B-401) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas. The Air Compression Therapy Recovery System simulates kneading and stroking of tissues by using an inflatable garment. This device is Over-The-Counter (OTC). It is intended for use by healthy adults who are over 21 years old.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K230500

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Name: Jiangsu MaxF Electric Appliance Co., Ltd
Establishment Registration Number: 3017153262
Address: NO.12, West Park Road, Rulin Town, Jintan District, Changzhou, China

Contact name: ZHANG JIANFANG
Tel: +86-15961228139
E-mail: 372601574@qq.com
Postal Code: 213200

Application Correspondent:

Name: Share Info (Guangzhou) Medical Consultant Ltd.
Contact Person: Ms. Cassie Lee
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8266 2446
Email: regulatory@share-info.com

2. Date of the summary prepared: October 25, 2023

3. Subject Device Information

Classification Name: Massager, powered inflatable tube
Trade Name: Air Compression Therapy Recovery System
Model Name: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601, MF-AWI.LED.A-601, MF-AWI.LED.B-601, MF-AWI.OLED.A-401, MF-AWI.LED.A-401, MF-AWI.LED.B-401
Review Panel: Physical Medicine
Product Code: IRP
Regulation Number: 890.5650
Regulatory Class: II

4. Predicate Device Information

Predicate Device 1 Information

Sponsor: Rapid Reboot Recovery Products, LLC

Trade Name: Rapid Reboot Compression Therapy System

Classification Name: Massager, powered inflatable tube

510(K) Number: K182668

Review Panel: Physical Medicine

Product Code: IRP

Regulation Number: 890.5650

Regulation Class: II

Predicate Device 2 Information

Sponsor: FOSHAN HONGFENG CO.,LTD.

Trade Name: Air compression therapy system

Classification Name: Massager, powered inflatable tube

510(K) Number: K201982

Review Panel: Physical Medicine

Product Code: IRP

Regulation Number: 890.5650

Regulation Class: II

5. Device Description

The Air Compression Therapy Recovery System (model: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601, MF-AWI.LED.A-601, MF-AWI.LED.B-601, MF-AWI.OLED.A-401, MF-AWI.LED.A-401, MF-AWI.LED.B-401) is a portable inflatable tube massage system which simulates kneading and stroking of leg, arm and hip by the use of inflatable air compression techniques. The device can be used to temporarily increase blood circulation and temporarily relieve minor muscle aches and pains. This device is Over-The-Counter (OTC). It is intended for use by healthy adults who are over 21 years old.

The device utilizes the pneumatically controlled chambers actuated by an electronically controlled air pump and air valve. The pump, air valve and other components are protectively housed within the ABS plastic enclosure of the control unit.

The device consists of a control unit, two RecoveryLeg (air boot with attached hose and hose connector), two RecoveryArm (air arm sleeve with attached hose and hose connector) and one RecoveryPants (air pants with two attached hoses and hose connectors). The RecoveryLeg, RecoveryArm and RecoveryPants work under the action of sensor and microprocessor. Software controls the timing and pressure reflected by the sensor, cycling airflow into and out of the boots, sleeves or pants to compress body.

The device is categorized to have long-term skin contact of greater than 30 days.

Environment of use of the device: Clinics, hospital, athlete training, and home environments.

6. Intended Use / Indications for Use

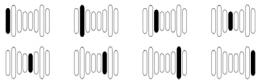
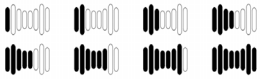
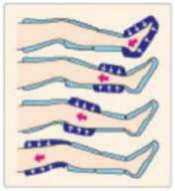
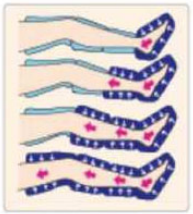
The Air Compression Therapy Recovery System (model: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601, MF-AWI.LED.A-601, MF-AWI.LED.B-601, MF-AWI.OLED.A-401, MF-AWI.LED.A-401, MF-AWI.LED.B-401) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas. The Air Compression Therapy Recovery System simulates kneading and stroking of tissues by using an inflatable garment. This device is Over-The-Counter (OTC). It is intended for use by healthy adults who are over 21 years old.

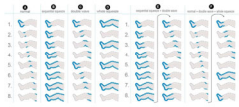
7. Comparison to predicate device and conclusion

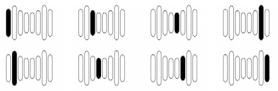
As compared to the predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device (Secondary)	Remark
Company	Jiangsu MaxF Electric Appliance Co., Ltd	Rapid Reboot Recovery Products, LLC	FOSHAN HONGFENG CO.,LTD.	--
Trade Name	Air Compression Therapy Recovery System (model: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601,MF-AWI.LED.A-601,MF-AWI.LED.B-601, MF-AWI.OLED.A-401,MF-AWI.LED.A-401,MF-AWI.LED.B-401)	Rapid Reboot Compression Therapy System	Air compression therapy system: FO-3001	--
Classification Name	Massager, Powered inflatable tube	Massager, powered inflatable tube	Massager, powered inflatable tube	Same
510(k) Number	K230500	K182668	K201982	--
Product Code	IRP	IRP	IRP	
Regulation Number	890.5650	890.5650	890.5650	Same
FDA Device Classification	II	II	II	Same
Review Panel	Physical Medicine	Physical Medicine	Physical Medicine	Same
Rx or OTC	OTC	OTC	OTC	Same
Intended Use / Indications for	The Air Compression Therapy Recovery	The Rapid Reboot Compression	Intended for home to temporarily relieve	Same

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device (Secondary)	Remark
Use	System (model: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601, MF-AWI.LED.A-601, MF-AWI.LED.B-601, MF-AWI.OLED.A-401, MF-AWI.LED.A-401, MF-AWI.LED.B-401) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas. The Air Compression Therapy Recovery System simulates kneading and stroking of tissues by using an inflatable garment. This device is Over-The-Counter (OTC). It is intended for use by healthy adults who are over 21 years old.	Therapy System is intended 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.	minor muscle aches and/or pains, promote blood circulation in treated areas.	
Treatment time	0-50mins	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	1-60mins	Similar Note 1
Treatment area	Leg (including of foot, calf, knee, upper leg) Hip (including of upper leg, glutes, hips, lower lack) Arm (including of entire arm, shoulder, upper chest and back)	Leg (including of foot, calf, knee, upper leg) Hip (including of upper leg, glutes, hips, lower lack) Arm (including of entire arm, shoulder, upper chest and back)	Leg	Same
Environment	Clinics, hospital, athlete	Clinics, hospital,	Not provided in the	Same

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device (Secondary)	Remark
of use	training, and home environments.	athlete training, and home environments	510k summary	
Modes	Mode of MF-AWI is listed as below: **Mode A: Pressure fills one chamber at a time and that chamber deflates while next chamber fills.** When the first chamber inflates to the selected pressure, the second chamber begins to inflate and the first chamber deflates. When the second chamber fully inflates, the third chamber begins to inflate and the second chamber deflates. Then the fourth, fifth, sixth, seventh and eighth inflate and deflate one by one.  **Mode B:** Pressure fills one chamber at a time. Each chamber remains inflated while the next one fills until all 8 chambers are inflated. Then, all the 8 chambers deflate together and the cycle repeats.  **Mode C: Pressure fills two chambers at a time and those two chambers deflate while the next two chambers fill.** The first and the second chambers inflate to the selected pressure at the same time. When	2 modes: "A" mode inflates and deflates chambers from bottom up (distal to proximal chambers), out at a time. “B” mode also inflates chambers from bottom up, but maintains pressure in lower chambers as works its way to top. Then all chambers release pressure at same time once all chambers have sequentially inflated. Mode A  Mode B 	6 chambers: A (Normal Mode): Chamber ① inflating till setup pressure or for 2 seconds, then hold air for 2 seconds, start deflating; chamber ② start like ①. Same way till chamber ⑥, pause for 3 seconds, then restart chamber ①②③④⑤⑥ again. B (Sequential Squeeze Mode): chamber ① inflating till set up pressure or for 28 seconds, then hold the pressure, chamber ② inflating, till setup pressure or for 28 seconds, then chamber ①② hold pressure in same time, then chamber ③ start inflating, same way till after chamber ⑥. Chamber ①②③④⑤⑥ deflating in same time for 3 seconds. Then repeat. C (Double Wave Mode: chamber ①② inflating till setup pressure or for 40 seconds, hold air for 2 seconds, then start deflating. Chamber ③④ start inflating till setup pressure or for 40 seconds, hold air for 2 seconds, then deflating, same way	Similar Note 2

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device (Secondary)	Remark
	chambers one and two are fully inflated, the third and the fourth chamber begin to inflate while the first and the second chambers begin to deflate. The cycle repeats through the 8 chambers.  **Mode D: Pressure fills two chambers at a time until all 8 are filled**. The first and the second chambers inflate to the selected pressure. Once fully inflated, the third and the fourth chambers begin to inflate until all 8 chambers are fully inflated. Then, all the 8 chambers deflate together and the cycle repeats.  **Mode E: Pressure fills one chamber at a time and that chamber deflates while next chamber fills.** When the first chamber inflates to the selected pressure, the third chamber begins to inflate and the first chamber deflates. When the third chamber fully inflates, the fifth chamber begins to inflate and the third chamber deflates. Then the seventh, second, fourth, sixth and eighth inflate and deflate one by one.		for chamber ③④ till chamber ⑤⑥, pause for 3 seconds. Then repeat. D (Whole Squeeze Mode): chamber ①②③④⑤⑥ inflating at the same time till setup pressure or for 90 seconds, then deflating in the same time for 3 seconds. Then repeat. E (Combined B + C): sequential squeeze + double wave F (Combined A + C + D): normal + double wave + whole squeeze. 4 and 8 chambers same as 6 chambers above. 	

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device (Secondary)	Remark
	 For MF-AWI.OLED.A-601 and MF-AWI.OLED.A-401 using 6 chambers and 4 chambers, the mode is the same as mode of MF-AWI as demonstrated above. For MF-AWI.LED.B-801,MF-AWI.OLED.A-601,MF-AWI.LED.A-601,MF-AWI.LED.B-601, MF-AWI.LED.A-401,MF-AWI.LED.B-401 They only has one mode (mode B).			
Output pressure range	0-40-80-120-160-200mmHg (Tolerance: -10% ~ +20%)	0-200 mmHg	30-110mmHg	Similar Note 1
Power source	100-240V, 50/60Hz	110VAC, 60Hz	100-127V/220-240V, 50/60Hz	Similar Note 3
Power	30W	30W	65 W	Same
Number of Chamber	4, 6, 8	4	4, 6, 8	Same
Photo/size of the control unit		10" x 6.5" x 5" 	 220*190*113mm	Similar Note 4

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device (Secondary)	Remark
	  140mm x 87mm x 280mm			
Housing materials	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure	Same
Compression Applicator Garments Boots/Sleeves /pants Material	TPU Nylon Composite	Nylon with a Polyurethane laminate	Not mentioned in the 510k summary	Similar Note 5
Photo/size of the boots	 1060mm x 345mm	 X-Short: 14” x 41” Short: 14” x 43” Medium: 14” x 45” Long: 14” x 48” X-Long: 14” x 52”  	 M:91*65cm L:100*74cm XL:110*70cm (Overlapping)	Similar Note 4

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device (Secondary)	Remark
Photo/size of the arm sleeves	 974mm x 325mm	 Regular: 18" x 38" Long: 18" x 44" 	No arm sleeves	Similar Note 4
Photo/size of the pants	 530mm x 730mm	 Regular: 26" x 32" Large: 26" 35" 	No pants	Similar Note 4
Safety feature	Button on control unit allow users to stop or pause therapy session at any time.	Button on display allows users to stop or pause therapy session at any time.	Power button on main unit allows user to stop therapy session at any time	Same
Mode of compression	Sequential	Sequential	Sequential	Same
Software/firmware/microprocessor control	Microprocessor	Microprocessor	Microprocessor	Same
Technology	Compressor and valve system which sequentially inflates cells of appliance.	Compressor and valve system which sequentially inflates cells of appliance.	Compressor and valve system which sequentially inflates inflatable chambers	Same
Electrical	ANSI-AAMI ES 60601-1	ANSI-AAMI ES	IEC 60601-1	Same

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device (Secondary)	Remark
safety, EMC, Bio-compatibility	IEC 60601-1-2 IEC 60601-1-11 ISO 10993-5 ISO 10993-10 ISO 10993-23	60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 10993-5 ISO 10993-10	IEC 60601-1-2 IEC 60601-1-11 ISO 10993-10 ISO 10993-5 ISO 10993-12	

Comparison in Detail(s):

Note 1:

Though there is a little difference of “treatment time” and “output pressure range” between the subject device and predicate devices, but treatment time is within the time range of predicate device 2, and output pressure range is within the predicate device 1. So, this slight difference will not raise any safety and effectiveness issue.

Note 2:

The mode A, B, C of subject device is similar to the Normal Mode, Sequential Squeeze Mode and Double Wave mode of predicate device 1 respectively. The inflating and deflating order of mode D, and E is different from predicate devices, but will not raise any safety and effectiveness issue.

Note 3:

Though there is difference of “power source” between the subject device and predicate device, but the subject device has been tested per ANSI/AAMI ES60601-1, IEC 60601-1-2, IEC60601-1-11. So, the difference of modes would not adversely impact safety and effectiveness.

Note 4:

Though there is difference of “Photo/size of the control unit”, “Photo/size of the boots”, “Photo/size of the arm sleeves”, “Photo/size of the pants sleeves” between subject device and predicate devices 1, but the difference would not adversely impact safety and effectiveness.

Note 5:

Though there is difference in material, the material of boots/sleeves/pants does not contact with skin during the massage, and the TPU Nylon Composite has been tested per ISO 10993-5, 10993-10 and ISO 10993-23, so the difference would not adversely impact safety and effectiveness.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary

The Air Compression Therapy Recovery System (model: MF-AWI, MF-AWI.LED.A-801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601, MF-AWI.LED.A-601, MF-AWI.LED.B-601, MF-AWI.OLED.A-401, MF-AWI.LED.A-401, MF-AWI.LED.B-401) has been evaluated the safety and performance by lab bench testing as following:

Title of the test	Device Description /Sample Size	Test Method/Applicable Standards	Acceptance criteria	Unexpected Results/ Significant Deviations	Test results
General requirements for basic safety and essential performance	The test sample is the final, finished product.	IEC 60601-1:2005/AMD 1:2012/AMD 2:2020	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Electromagnetic disturbances	The test sample is the final, finished product.	IEC 60601-1-2:2014+A1: 2020	No degradation of performance was found during test or Lower than limits of measurement	NA	Pass
Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	The test sample is the final, finished product.	IEC 60601-1-11:2015/AMD1:2020	The device operates normally, and can provide basic safety and essential performance.	NA	Pass

2) Biocompatibility testing

- ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2021Biological Evaluation of Medical Devices - Part 10: Tests skin sensitization
- ISO 10993-23: 2021 Biological Evaluation of Medical Devices - Part 23: Test for irritation

3) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as

a “moderate” level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Cybersecurity

The subject device no any external interfaces, according to FDA guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”, no need cybersecurity evaluation.

8.2 Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

9. Final Conclusion：

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K182668 and K201982.