May 30, 2019

Maxstar Industrial Co., Ltd
% Chris Park
General Manager
Med.com
1809 Holland Dr
Somerset, New Jersey 08873

Re: K173158
Trade/Device Name: Air Relax/ Compressible Limb Sleeve System Model No. UAM-8100, UAM-8100N
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: April 19, 2019
Received: April 30, 2019

Dear Chris Park:

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.


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 J. Pinto -S

Vivek Pinto, 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
Indications for Use

Device Name
Air Relax/ Compressible Limb Sleeve System Model No. UAM-8100, UAM-8100N

Indications for Use (Describe)
UAM-8100, UAM-8100N is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as : Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.

Type of Use (Select one or both, as applicable)

- [X] 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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This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: Sep, 26, 2017

I. SUBMITTER

Submitter’s Name: Maxstar Industrial Co Ltd
Submitter’s Address: 152-12, Hwanggeum-ro, 23 beon-gil, Yangchon-eup, Gimpo-si, Gyeonggi-do, Korea
Submitter’s Telephone: +82 31 989 3543
Contact person: Kevin Jung (speed1@maxstar.co.kr) / Sales Manager
Official Correspondent: J-R Kim
Address: 1809 holland dr, somerset, NJ, 08873, USA
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II. DEVICE

Trade/proprietary Name: Air Relax/ Compressible Limb Sleeve System
Model No.: UAM-8100, UAM-8100N
Common or Usual Name: Powered Inflatable Tube Massager
Classification Name: Massager, Powered Inflatable Tube
Regulation Number: 21 CFR 884.5160
Product Code: IRP (21 CFR 890.5650)
Regulatory Class: Class II

III. PREDICATE DEVICE

Primary Manufacturer: Maxstar Industrial Co Ltd
Device Name: Compressible Limb Sleeve System
510(k) Number: K130385
Regulation Name: Massager, Powered Inflatable Tube
Regulation Number: 21 CFR 884.5160
Regulatory Class: Class II
IV. DEVICE DESCRIPTION

UAM-8100, UAM-8100N is a system to improve the blood circulation of patients and User can use it personally under their doctor's indication and guidance.

UAM-8100, UAM-8100N is combined with leg and foot garments. The leg garment has four air chambers operated by a controller. The leg garment is compressed sequentially in order of foot, calf, and thigh, and then fresh air is injected inside the leg garment through holes.

V. INDICATIONS FOR USE:

UAM-8100, UAM-8100N is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.

VI. PREDICATE COMPARISON

Identification of predicate device
Predicate Device
- 510(k) number: k130385
- Name: Compressible limb Sleeve System
- Model: UAM-8100
- Company: MAXSTAR CO LTD
- Classification: 2

MAXSTAR Co., Ltd. believes that Compressible Limb Sleeve System Model: UAM-8100, UAM-8100N) is substantially equivalent in intended use, principles of operation, and technological characteristics to the predicate devices presented above and few differences between previous model as
1. Software version
2. Change of inflation and deflation timing due to software version change
3. Add the Trade name “Air Relax”
4. Additional accessory (XXL size Garments Sleeve)
5. Additional model: New type of model UAM-8100N: Color (Navy)
But do not raise new types of safety or effectiveness issues, as further discussed below.

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

Biocompatibility:
Testing was conducted in accordance with AAMI / ANSI / ISO 10993-5:2009/(R) 2014, Biological Evaluation of Medical Devices-- Part 5: Tests for In Vitro Cytotoxicity (L929 Assay) and AAMI / ANSI / ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization. (Vaginal Irritation and Guinea Pig Maximization Sensitization)

Electrical Safety:

Electromagnetic Compatibility:
Testing was conducted in accordance with IEC 60601-1-2:2007 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

Software:
Software verification and validation testing as recommended in FDA’s Guidance Document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” (May 11, 2005)

VIII. Product Comparison Summary
The proposed device and the predicate device have the similar intended use, mechanism of action, principle of operation, algorithm, and cuff. The proposed device is different than the predicate device in that the proposed device has different inflation and deflation times, there is a different product color for UAM-8100N, a new compression garment size has been added, a product brand name has been added, the product label K130385 has been updated, and software has been modified. The results of the software verification and validation testing demonstrated that the differences between the proposed device and the predicate device do not raise questions regarding its safety and effectiveness.

IX. Substantially Equivalent (SE) Conclusion
Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device