June 17, 2021

Fist Assist Devices, LLC
Tej Singh
CEO, Founder
25599 Fernhill Road
Los Altos, California 94024

Re: K210281
Trade/Device Name: Fist Assist Devices Model FA-1
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: March 19, 2021
Received: March 22, 2021

Dear Tej Singh:

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,

For Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210281

Device Name
Fist Assist Devices Model FA-1

Indications for Use *(Describe)*
The Fist Assist Model FA-1 is an arm massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

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

[as required by 21 CFR 807.92(c)]

Fist Assist Devices, Model FA-1

510(k) K210281

DATE PREPARED:	May 25, 2021
APPLICANT	Fist Assist Devices, LLC. 25599 Fernhill Dr. Los Altos Hills, CA 94024
CONTACT	Tej Singh, MD, MBA CEO and Founder Fist Assist Devices, LLC Email: fistassistdevices@gmail.com
TRADE NAME:	Fist Assist Devices Model FA-1
DEVICE CLASSIFICATION:	Class II per 21 CFR 890.5650
CLASSIFICATION NAME:	Powered Inflatable Tube Massager
PRODUCT CODE	IRP
PREDICATE DEVICES:	1. NormaTec Pulse 2.0 and Pulse Pro 2.0 (K183169) 2. Fig LLC, PowerPlay PPRT-01 (K122154) 3. ManaMed Inc., PlasmaFlight (K200351)

INDICATION FOR USE:

The Fist Assist Model FA-1 is an arm air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

DEVICE DESCRIPTION:

The Fist Assist Model FA-1 is a wearable, non-sterile, battery operated, intermittent pneumatic compression device for use on the arm over clothing. It is composed of two major components that are permanently attached to one another:

1. the control module that contains the electronics with miniature pump and
2. the wrap made of elastic cloth that holds the control module and internal air bladder and uses hook tape for attachment to any part of the wrap exterior.

The control module and wrap are integral and permanently attached. It is powered by (2) AA batteries.

The Fist Assist Model FA-1 has a single operation mode. When powered on by depressing the single push button switch, it goes through pressure cycles wherein the air bladder inflates to 60 mmHg and is held at that pressure for 20 seconds; the air bladder is then deflated and a minimal pressure of 10 mmHg (or less) and is held for 55 seconds until the next inflation to 60 mmHg begins again. The cycle repeats continuously until the power is turned off using the single push button switch. The device will turn off automatically after 1 hour of continuous use. When wearing this device, the device should only be used over full clothing and never on direct skin.

COMPARISON WITH PREDICATE DEVICE:

The indications for use of the Model FA-1 and its primary predicate device is identical. Additionally, there are specific design features of the Model FA-1 device that are similar to the predicate devices. Table 5-1 below provides a summary of the comparison of the Model FA-1 to its predicates. Further information on predicate comparison is located in Section 12, Substantial Equivalence Discussion.

Table 5-1 Comparison Summary of the Model FA-1 to Predicates

	Subject Device: Fist Assist Devices, LLC Model FA-1	**Primary Predicate Device: NormaTec Industries, LP Pulse 2.0 and Pulse Pro 2.0**	**Predicate Device: Fig, LLC PowerPlay PPRT-01**	**Predicate Device ManaMed, Inc. PlasmaFlight**
Manufacturer	Fist Assist Devices, LLC	NormaTec Industries, LP	Fig, LLC	ManaMed, Inc
510k Number	**K210281**	K183169	K122154	K200351
Indications for Use	The Fist Assist, Model FA-1 is an arm air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	The NormaTec Pulse and Pulse Pro are air pressure massagers intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	The PowerPlay model PPRT-01 is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue with the hands and by use of inflatable pressure wraps. This device can be used to: temporarily increase blood circulation in the treated areas; and temporary relief of minor muscle aches and pains	The PlasmaFlight is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue with the hands and by use of inflatable pressure wraps. This device can be used to: temporarily increase blood circulation in the treated areas; and temporary relief of minor muscle aches and pains.
Technology	A single bladder wrap actuated by an electronically controlled small internal air pump and valve system.	Compressor and valve system that sequentially inflates cells of appliance. Bluetooth communication ability.	Single bladder compression wraps actuated by and electronically controlled air pump unit and solenoid valves	Airbladder encased in a covering controlled by a micropump controlled by microprocessor

	Subject Device: Fist Assist Devices, LLC Model FA-1	**Primary Predicate Device: NormaTec Industries, LP Pulse 2.0 and Pulse Pro 2.0**	**Predicate Device: Fig, LLC PowerPlay PPRT-01**	**Predicate Device ManaMed, Inc. PlasmaFlight**
Compliance with EMC/IEC Voluntary standards?	Yes, ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	Yes, ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	Information Not Available	Compliant to Voluntary Standards
Device Pressure Range	10-60mmHg	0-110 mmHg	30-70 mmHg	0-55 mmHg
Weight	0.35 pounds	3.6 pounds	1.1 pounds	.51 pounds
Housing Materials	Molded ABS enclosure (94VB)	Molded ABS enclosure (94V0)	Plastic Housing	Plastic Case
Sterilization Method	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Max. Inflation Pressure	60 mmHg, preprogrammed	110mmHg, set by user	70mmHg, set by user	55 mmHg
Deflation Hold Time	55 seconds	Default 30 sec, but can be manually adjusted between 15 to 90 sec.	Approximately 30 seconds for each port used, preprogrammed	Information Not Available
Prescription Device	No (OTC)	No (OTC)	No (OTC)	No (OTC)

	Subject Device: Fist Assist Devices, LLC Model FA-1	**Primary Predicate Device: NormaTec Industries, LP Pulse 2.0 and Pulse Pro 2.0**	**Predicate Device: Fig, LLC PowerPlay PPRT-01**	**Predicate Device ManaMed, Inc. PlasmaFlight**
Pre-Programmed Treatment time	60-minute preprogrammed treatment. Cycle can be stopped by user.	10 minutes to 2h55 minute treatment time set by user. Cycle can be stopped by user.	20 minutes preprogrammed per port, up to 60-minute total treatment if all 3 ports are used. Cycle can be stopped by user.	60-minute preprogrammed treatment.

NON-CLINICAL TESTING / PERFORMANCE DATA:

Non-clinical testing of the Model FA-1 was performed following applicable standards.

TRANSPORTATION TESTING

Packaging testing of the Model FA-1 was performed to ISTA 3A-2018, General Simulation Performance Test Procedure for Parcel Delivery System 70kg (or 150lbs.) or less using the small packaging process sequence of testing. The results of test concluded that all units tested met the requirements of standard.

BIOCOMPATIBILITY

The biocompatibility of the materials has not been verified by the FDA and contact of the cuffs/accessories to direct skin may lead to skin irritation, skin sensitization and/or cytotoxicity.

SOFTWARE VALIDATION

Software validation was performed using the "General Principle of Software Validations; Final Guidance for Industry and FDA Staff, dated January 11, 2002". All tested variables were found to meet acceptance criteria established.

ELECTRICAL TESTING

Electrical Testing was performed using the test standards AAMI/ANSI ES 60601-1:2005/(R)2012 And A1:2012*: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance*. Testing concluded that the Device met all test requirements for the electrical safety.

EMC EVALUATION

Electromagnetic Compatibility (EMC) testing of the Device was performed using the test standard IEC 60601-1-2:2014: *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests*. Testing concluded that the Device met all test requirements for EMC.

BENCH TESTING

Mechanical testing was performed to confirm the functionality of key process parameters were performed. All parameters tested were found to meet acceptance criteria established.

CONCLUSION:

The Model FA-1 is indicated for the identical intended use and similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate devices. Performance data demonstrates that the device functions as intended. Therefore, the Model FA-1 is substantially equivalent to the predicate device.