August 22, 2022

Foggiare Technologies LLC
℅ Jay Mansour
Principal
Mansour Consulting LLC
845 Aronson Lake Court
Roswell, Georgia 30075

Re: K201730
Trade/Device Name: IAF-SYSTEM
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: July 6, 2022
Received: July 7, 2022

Dear Jay Mansour:

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,

Tushar Bansal, PhD
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201730

Device Name
IAF-SYSTEM

Indications for Use *(Describe)*
IAF-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. IAF-SYSTEM 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #K201730

510k Summary:

As required by 21 CFR 807.92 (c)

1 - Date Summary Prepared: August 13, 2022

2 - Owner/Submitter/Sponsor/Applicant information:

OWNER/SUBMITTER/SPONSOR/APPLICANT
Contact name: Edouard Sezionale- Foggiare Technologies LLC
Title: owner/CEO
Telephone: (561) 923-9161
Email address: thierry@foggiare.com
Address: 426 E Palmetto Park Rd.
Boca Raton, FL 33432 USA

APPLICATION CORRESPONDENT
Contact name: Jay Mansour, MSQA, BE, RAC- Mansour Consulting LLC
Title: regulatory consultant- Principal
Telephone: (678) 908-8180
Email address: jay@mansourconsulting.com
Address: 845 Aronson Lake Court
Roswell, GA 30075 USA

3 - Device Information:

Common/usual/classification name:

massager, powered inflatable tube
Device name:

	Device Model Name	Model Number
1	IAF-SYSTEM	(NO MODEL NUMBER)

FDA 3 Letter Code	IRP
FDA regulation number: 21 CFR	890.5650
Regulation medical specialty	Physical Medicine
Review panel	Physical Medicine
Class	2

4 - Substantial equivalency is claimed against the following predicate device(s):

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Primary Predicate?**
k182668	Rapid Reboot Compression Therapy System	Rapid Reboot Recovery Products, LLC	Yes

5 - Description of the device

Subject 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 four (4) compression chambers. The compression massage direction is from limb end to body center. 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

6 - Intended Use + indications for use

Intended Use:	The IAF-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 IAF-SYSTEM simulates kneading and stroking of tissues by using an inflatable garment.
indications for use:	

7 - Basis for determination of substantial equivalency:

(a) Indications for use:
The indication for use is identical to the predicate's.

(b) Technological characteristics:
The technological characteristics are substantially equivalent to the predicate device, meeting the same technical standards.

Substantial equivalency between our device and predicate device is tabulated below:

Device	Subject Device	Primary Predicate	Comparison
Manufacturer	DAM SRL	Rapid Reboot Recovery Products, LLC	NA
510(k) Number	TO BE DETERMINED	K182668	NA
Model Name	IAF-SYSTEM	Rapid Reboot Compression Therapy System	NA
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Same
Indications for Use (IFU)	The IAF-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 IAF-SYSTEM simulates kneading and stroking of tissues by using an inflatable garment.	The Rapid Reboot Compression 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.	Same
OTC or Rx	OTC	OTC	Same
Environment of Use:	Clinics, hospital, athlete training, and home environment.	Clinics, hospital, athlete training, and home environments	Same
Standards	ANSI AAMI ES60601- 1:2005/ (R)2012 And A1:2012 IEC 60601-1-2 Edition 4.0 2014-02	IEC 60601-1:2014; IEC 60601-1-2:2014	Same
	Biocompatibility not required	EN ISO 10993-5:2009 & EN ISO 10993-10:2010	Different. Biocompatibility not required for subject device, as users wear clothing under the garments. No direct contact
Mode of Compression	Sequential"Seawave"/ Peristaltic	Sequential/Peristaltic	Same
Power Source	120 V, 50Hz	120V, 60Hz	Same

Therapy Time	User determines therapy time. Choose from 10, 20,25 or 30 minute session time.	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	Same
Max Pressure Min Pressure	0-119 mmHg	0-200 mmHg	Different. Subject device provides substantially equivalent pressure, despite the different maximum pressure
Number of Chambers	4 Chambers	4 Chambers	Same
Compression Applicator Garments Sleeve Material	Nylon with a Polyurethane laminate	Nylon with a Polyurethane laminate	Same
Housing Materials And Constructions	Molded ABS enclosure	Molded ABS enclosure	Same
Patient contact	Non-conductive attachments	Non-conductive attachments	Same
Power Consumption	400 W	30W	Different due to physical configuration

<table>
<tr>
<td>Cycle time</td>
<td>Leg (consisting of foot, calf, knee, upper leg)
The cycle time for all programs is tabulated below.
The first cycle can be different from the following ones, because it starts with totally empty sectors, while the following cycles can start with some air in the sectors; moreover, in many programs the cycles change over the course of the program. This is illustrated within the user manual.
<table>
<tr><th></th><th>minutes</th><th colspan="4">seconds</th></tr>
<tr><th>Prog. n.</th><th>Treatment time</th><th>Sector pause</th><th>cycle pause</th><th>1st cycle time</th><th>subsequent cycle time</th></tr>
<tr><td>1</td><td>25</td><td>1</td><td>3</td><td>50</td><td>38</td></tr>
<tr><td>2</td><td>25</td><td>1</td><td>3</td><td>47</td><td>41</td></tr>
<tr><td>3</td><td>25</td><td>1</td><td>3</td><td>46</td><td>33</td></tr>
<tr><td>4</td><td>25</td><td>2</td><td>4</td><td>49</td><td>39</td></tr>
<tr><td>5</td><td>25</td><td>2</td><td>4</td><td>69</td><td>60</td></tr>
<tr><td>6</td><td>25</td><td>2</td><td>4</td><td>80</td><td>68</td></tr>
<tr><td>7</td><td>25</td><td>1</td><td>3</td><td>97</td><td>35</td></tr>
<tr><td>8</td><td>30</td><td>1</td><td>3</td><td>260</td><td>140</td></tr>
<tr><td>9</td><td>25</td><td>1</td><td>3</td><td>65</td><td>98</td></tr>
<tr><td>10</td><td>20</td><td>2</td><td>4</td><td>206</td><td>203</td></tr>
<tr><td>11</td><td>30</td><td>2</td><td>3</td><td>34</td><td>28</td></tr>
<tr><td>12</td><td>20</td><td>2</td><td>3</td><td>34</td><td>33</td></tr>
</table>
The cycle time is the time needed to fill air in the sectors with set pressure in the set sequence + sectors pause.

Sector pause is the time between the end of fill in of air in a sector and the start of fill in of the air in the sequel one.
The cycle pause is the time between the end of a cycle and the start of the next one.
1st cycle time is the time needed for the 1st complete cycle (it needs a little more because start with total empty sectors).
Subsequent cycle time is the time need for other cycles (being little bit shorter because the sectors are not totally empty).
Exception in program 9: This program includes a first section where the plantar thrust provides pressure starting from the bottom-base of the thigh, then mid-thigh, then knee and calf, and finally knee and ankle. The effect is therefore drainage from the top. After that, it starts a treatment like program 1.</td>
<td>1 min 20 sec

3</td>
<td>Same and different depending on the program. See below.

Information below lists 1st cycle, subsequent cycle and predicate cycle, respectively, all in seconds, comparing each of the 12 programs with the predicate cycle time:

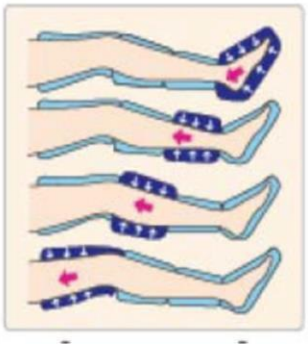
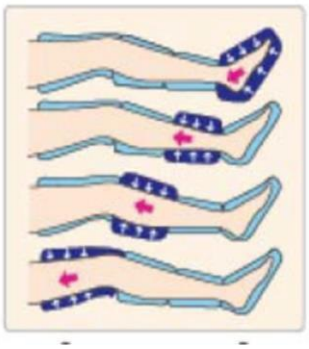
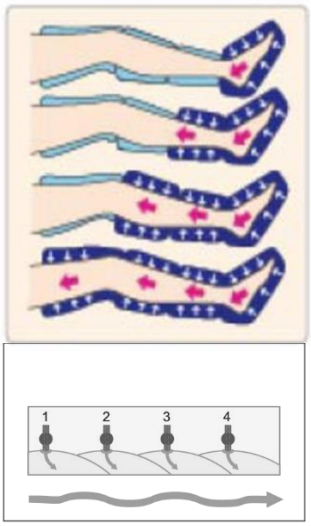
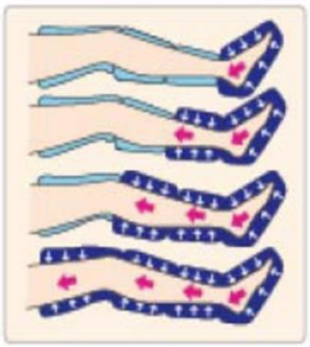
Program 1: 50 / 38 / 80
Program 2: 47 / 41 / 80
Program 3: 46 /33 / 80
Program 4: 49 / 39 / 80
Program 5: 69 / 60 / 80
Program 6: 80 / 68 / 80
Program 7: 97 / 35 / 80
Program 8: 260/140/80
Program 9: 65 / 98 / 80
Program 10: 206/203/80
Program 11: 34 / 28 /80
Program 12: 34 / 33 / 80

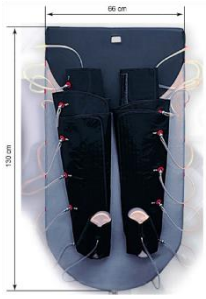
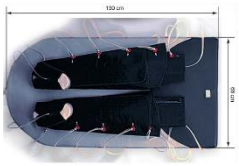
Program 6 provides the same exact (1st) cycle time as predicate device.

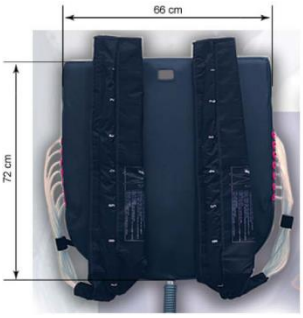
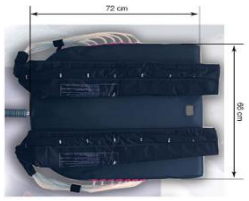
All other programs offer substantially the same cycle time, varying between 34 and 260 seconds (for 1st cycle) and between 33 and 203 seconds (for subsequent cycles).

The differences in cycle times are within the same order of magnitude as predicate device, and do not raise new concerns.</td>
</tr>
</table>

Size	49" x 21" x 14.5"	10” x 6.5” x 5”	Same. (Tabletop or handheld portable)
Weight	77 pounds with base	5.8 pounds	Different due to physical configuration
Modes (Inflation sequences, all preprogrammed)	2 modes: "A" mode inflates and deflates chambers from bottom up (distal to proximal chambers), one at a time. "B" mode also inflates chambers from bottom up, but maintains pressure in selected chambers as works its way to top. Then all chambers release pressure at same time once all chambers have sequentially inflated.	2 modes: "A" mode inflates and deflates chambers from bottom up (distal to proximal chambers), one 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.	Same. Both devices have sequential mode (distal to proximal chambers).

Modes (visual description)	“Sequential:”  With "lock" on specific area	Mode A: 	Same
	Mode seawave:  **"SEA WAVE" LEG-PIECE** With overlapping bands, pressure which decreases towards the top and programmable control of sectors, the flow is physiological.	Mode B: 	Same The machine permits applying a set pressure in a targeted way to each single "lock" sector to determine the effect and effectiveness on the patient. One or more sectors can be kept under pressure so that during program execution, these do not deflate during the cycle.

“Leg” Attachment	Leg (consisting of foot, calf, knee, upper leg)	Leg (consisting of foot, calf, knee, upper leg)	Same
Leg Attachment Photos			Same
Leg Attachment Sizes	51"x 26" 	X-Short: 14” x 41” Short: 14” x 43” Medium: 14” x 45” Long: 14” x 48” X-Long: 14” x 52”	Different. Slight variation.
“Hip” Attachment	Hip (consisting of upper legs, glutes, hips, lower back)	Hip (consisting of upper legs, glutes, hips, lower back)	Same

"Arm" Attachment	Arm (consisting of entire arm, shoulder, upper chest and back)	Arm (consisting of entire arm, shoulder, upper chest and back)	Same
Arm Attachment Photos			Same.
Arm Attachment Sizes	One size: 26" x 28 " 	Regular: 18" x 38" Long: 18" x 44"	Same. Slight variation.
Safety Features	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
SW/Firmware/ Microprocessor Control	Microprocessor	Microprocessor	Same
Technology	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	Same

(c) Non-clinical tests- brief discussion:
Safety testing and EMC testing successfully completed.
In particular, the following tests were performed:

1- Earth circuit continuity test, leakage current, current absorption, current absorption: Summary of findings- device complies with these IEC 60601-1 safety requirements, in the lab as well as on production units (tests are conducted on on-going basis).

2- Main switch, air hose connector, delivered pressure, display function, programs, top card function, safety pressure switch intervention, maximum setting pressure, integrity of the inflatable parts (multiple)

Summary of findings- device complies with the acceptance criteria of these various tests, documenting that safety and effectiveness are achieved on validation units and on production units (tests are conducted on on-going basis).

(d) Clinical tests- brief discussion
Not applicable. No clinical tests were conducted.

(e) Non-clinical and clinical tests- conclusions drawn demonstrating that the device is as safe and as effective, and performs as well as the predicate device(s):
Safety of subject device is confirmed via testing. Effectiveness is ensured by similar parameter of a well-understood device mechanism.