February 11, 2021

Eezcare Medical Corp
% John Gillespy
President
FDA 510k Consultants, LLC
1100 Del Lago Cir, Ste 104
Palm Beach Gardens, Florida 33410

Re: K193662
Trade/Device Name: Ezlymph, Ezlymph M
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 7, 2021
Received: January 11, 2021

Dear John Gillespy:

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,

Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*

K193662

Device Name

EzLymph and EzLymph M

Indications for Use *(Describe)*

EzLymph and EzLymph M are intended to treat lymphedema.

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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Section 5 – 510(k) Summary

1. 510(k) Submitter:

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2. Company Contact: Michelle C. Mitchell

3. Date of Submission: December 29, 2019

4. 510(k) Preparer:

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Phone: 386-243-4332
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5. Device Classification:

Trade name:	**EzLymph, EzLymph M**
Common name:	Lymphedema Pump System
Device:	Sleeve, Limb, Compressible
Class:	II
Product Code:	JOW

6. Predicate:

	Applicant:	ArjoHuntleigh AB (Sweden)
	Device:	Hydroven 3 Pump, Hydroven FPR Pump, Hydroven Garments
	510(k) Number:	K910188
Reference:	Applicant:	Tactile Medical
	Device:	Flexitouch System
	510(k) Number:	K170216

7. Device Description… **EzLymph** and **EzLymph M** is a pump system intended to apply intermittent pneumatic compression (IPC) to arms and legs to relieve the discomfort of lymphedema (see image of device in Figure 1 below).

   The device helps move the flow of lymphatic and venous fluid throughout the extremities by stimulating muscles within the affected extremity. This action mimics natural muscle contractions, improves circulation, and moves excess fluid back to the circulatory system so edema can be eliminated from the body.

   System components include (a) a mains-powered, portable pneumatic pump with a pressure-control knob and on/off switch (the device contains no control panel or microprocessor circuit); (b) connecting air hoses; and (c) compression garments attached

to patient limbs. In addition, garment inserts allow increase in circumference of arm and leg garments.

The pump intermittently releases compressed air through the tubing into inflating and deflating bladders within cuffs that are wrapped separately around the patient's upper and lower limbs (full arm, full leg, and half leg).

EzLymph and **EzLymph M** is intended for home use under the care of personnel authorized and trained to treat lymphedema. The device is intended for patients at risk for the medical condition. The system is portable.

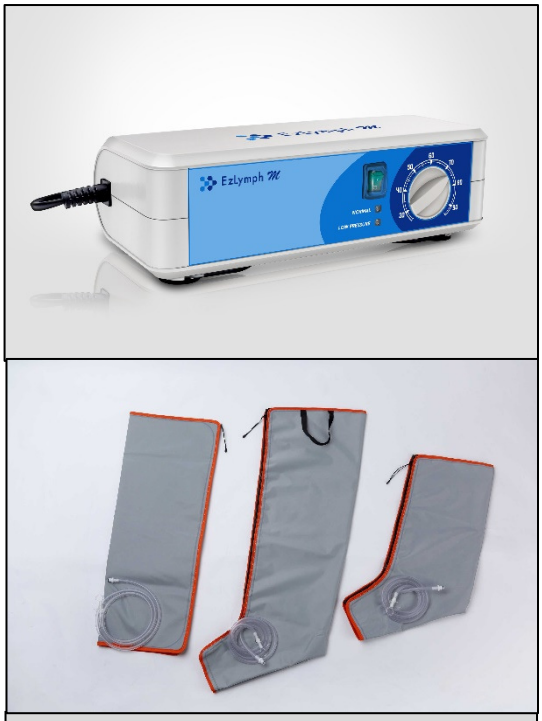

Figure 1 – EzLymph Pump and Garments

8. Mechanism of Action… Intermittent pneumatic compression of air inflates and deflates cuffs attached to affected extremities.

9. Indications For Use… Intended to treat lymphedema.

   The device is intended for prescription use only.

10. Comparison To Predicate & Reference Devices

    The subject and predicate devices share the same:

- Intended use – To apply intermittent pneumatic compression to arms and legs to relieve the discomfort of lymphedema.
- Indications for use – To treat lymphedema (the predicate also claims other indications, as noted in Table 5).
- System design – Portable pump, air hoses, compression garments.
- Number of models – Two.
- Garment styles – Arm, leg.
- Compression methods – Uniform, sequential.
- Compression cycle lengths – 180 seconds.
- Air chambers – Single chamber, multiple chamber.
- Multiple garments – Both devices allow treatment with 2 garments.
- Mode of operation – Continuous.
- Energy sources – Mains power.
- Materials – ABS plastic (pump case) and biocompatible fabric (garments).
- Reusability – Reusable pump and air tubing; garments are single-patient use.

Minor differences between the subject and predicate devices include:

- Number of compression chambers – While both offer single- and multiple-chamber models, for the latter the subject provides 4 chambers compared to the predicate's 3 chambers.
- Compression cycle sequence – Both offer 180-second cycles except that the predicate increases cycle length to 120 seconds for cycles that include calf or thigh; since application is continuous over long time periods (days and weeks, not hours or minutes), this difference is immaterial.

The reference device demonstrates substantial equivalence for one physical characteristic, pressure range, for EzLymph.

Table 5 - Comparison Table

Characteristics	Subject Device	Predicate Device[1]	SE Comparison
Device Name	EzLymph, EzLymph M	Hydroven 3 Pump, Hydroven FPR Pump, Hydroven Garments	NA
Manufacturer	Ezcare Medical Corp (Taiwan)	ArjoHuntleigh AB (Sweden)	NA
Estab Registration #	3003801933	3007420694	NA
510k Number	Applied For	K910188	NA
Device Photo (Pump & Air Hoses)			SE--both portable pumps
Device Photo (Calf/Thigh Garment)			SE--same basic design
Class	II	II	SE
Regulation #	870.5800	870.5800	SE
Product Code	JOW	JOW	SE
Common Description	Lymphedema Pump	Lymphedema Pump	SE
Medical Specialty	Cardiovascular	Cardiovascular	SE
Submission Type	510(k)	510(k)	SE

[1] Comparison data for the reference device, Flexitouch (K170216), is shown in "Pressure Range" characteristic on Page 5.0-5.

Intended Use	To apply intermittent pneumatic compression to arms and legs to relieve the discomfort of lymphedema.	To apply intermittent pneumatic compression to arms and legs to treat conditions listed in IFU.	SE--subject intended use is subset of predicate's
Indication For Use	EzLymph & EzLymph M are intended to treat lymphedema.	Intermittent Pneumatic Compression (IPC) is effective in treatment of following clinical conditions, when combined with an individualized monitoring program: Edema (dependent & traumatic), Lymphedema, (primary and secondary), Chronic venous insufficiency, Post phlebotic syndrome, and Acute & chronic wounds including venous leg ulcers & post-surgical wounds. IPC may also be beneficial in management of: Fixed flexion deformity, Arthritic conditions, Lower limb pain due to trauma or surgery, and Lipedema. Selection should be based upon a holistic assessment of patients' individual care needs.	SE--subject intended use (and IFU) is subset of predicate's
Target Population	Sufferers of lymphedema	Sufferers of lymphedema or other clinical conditions listed in IFU	SE--subject intended use is subset of predicate's
Anatomical Site	Arm/Leg	Arm/Leg	SE
Where Used	Home	Home	SE
Rx/OTC/Both	Rx Only	Rx Only	SE

Physical Characteristics--Overall

System Description	Portable pump, connecting air hoses, & compressible limb sleeves	Portable pump, connecting air hoses, & compressible limb sleeves	SE
Working Principle	Pneumatic pump supplies compressed air to inflate compression garments attached to patient limbs	Pneumatic pump supplies compressed air to inflate compression garments attached to patient limbs	SE

Physical Characteristics--Compression Garment

Garment Styles	Full Arm, Half Leg, Full Leg	Full Arm, Half Leg, Full Leg	SE
Garment Sizes	EzLymph--Arm (S,M), Leg (Half,S,M,L); EzLymph M--Arm (S,M), Leg (Half,S,M,L)	Hydroven 3--Single-Chamber Arm (4 lengths), Leg (6 lengths); Triple-Chamber Arm (2 lengths), Leg (6 lengths); Hydroven FPR (all triple-chamber)--Arm (2 lengths), Leg (6 lengths).	SE--both offer multiple arm and leg sizes
Garment Inserts	Allow increase in circumference of arm and leg garments.	Allow increase in circumference of arm and leg garments.	SE
Number of Air Chambers (Bladders)	EzLymph--1 (arm, leg) and 4 connected bags (arm, leg); EzLymph M--4 independent bags (arm, leg)	Hydroven 3--1 (arm, leg) & 3 connectd bags (arm,leg); Hydroven FPR--3 indepen-dent bags (arm, leg).	SE--minor difference in number of chambers
Compression--Uniform	EzLymph (1 & 4-chamber garments)--Inflate 90 sec, then deflate 90 sec. Cycle time 180 sec.	Hydroven 3 (1-chamber garments)--Inflate 90 sec, then deflate 90 sec. Cycle time 180 sec.	SE
Compression--Sequential	EzLymph M (4-chamber)--Inflate sequentially from distal (120, 90, 60, & 30 sec respectively), with 10% pressure decrease with each subsequent chamber moving up garment. Then deflate from proximal (60 sec). Cycle time 180 sec.	Hydroven 3 & FPR (3-chamber)--Inflate sequentially from distal (114, 76, & 38 sec). Then deflate from proximal (66 sec). Cycle time 180 sec.	SE--minor difference in number of chambers
Multiple Garments	2 garments can be used by alternating for every 90 sec. Cycle time is 180 sec (EzLymph only).	2 garments can be used by alternating for every 90 sec. Cycle time is 180 sec (Hydroven 3 only).	SE
Mode of Operation	Continuous	Continuous	SE
Pressure Range	EzLymph: 30-75 mmHg +/- 10% EzLymph M: 30-90 mmHg +/- 10%	Predicate: 30-100 mmHg +/- 5% Reference: 30-75 mmHg	EzLymph: SE--minor difference w/reference EzLymph M: SE--minor difference w/predicate

Physical Characteristics--Pump

Dimensions (mm)	280L x 140W x 70H	270L x 150W x 105H (Hydroven 3) or 130H (FPR)	SE--minor difference
Weight	1.7 kg (3.75lb)	2.4 kg (5.3 lb)	SE--minor difference
Energy Source (Mains)	AC 100V-230V (60/50 Hz)	AC 120V (60 Hz)	SE--minor difference
Fuse Rating	1A 250V/T1A 250V	F500 mAH 250V	SE--minor difference

Ingress Protection	IP21	IPX0	SE--minor difference
Control Panel	Mechanical	Not provided	SE
Operating Temp	5C to 40C	10C to 40C	SE--minor difference
Storage/Transport	-20C to 70C	-20C to 50C	SE--minor difference
Relative Humidity	<93% RH non-condensing	30%-75% (non-condensng)	SE--minor difference
Garment Material (Patient Contact)	Nylon fabric with TPU coating	Not provided	SE--subject passed biocompatibility testing
Case Material	ABS plastic	ABS plastic	SE
Components & Accessories			
Components	Pump, air hoses, garments	Pump, air hoses, garments	SE
Accessories	User manual	User manual	SE

Non-Clinical Testing

EzLymph and **EzLymph M** passed the following non-clinical tests, all of which were performed to current FDA-recognized standards:

- Electrical Safety… IEC 60601-1:2005, Mod
- EMC… IEC 60601-1-2:2014
- Usability Engineering… IEC 62366-1:2015
- Risk Management… ISO 14971:2007
- Home Healthcare… IEC 60601-1-11:2015

The device passed pump functionality testing and garments pressure cyclic testing.

Cybersecurity

EzLymph and **EzLymph M** is in compliance with FDA's guidance, "Management of Cybersecurity in Medical Devices" (2014). The device is not capable of connecting (wirelessly or hard-wired) to another device, to the Internet or other network, or to portable media (e.g., USB or CD).

Substantial Equivalence

EzLymph and **EzLymph M** successfully followed the pathway to Substantial Equivalence in the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" (2014). The steps are summarized below:

- The predicate device is legally marketed and was found substantially equivalent through 510(k) premarket submission.
- The subject and predicate devices have the same intended use.
- Technological differences between the subject and predicate were evaluated; none of the differences raised different issues of safety and effectiveness.
- The following methods for evaluation of the effects of different characteristics on safety and effectiveness were deemed acceptable—testing for electrical safety,

EMC, usability engineering, home healthcare, and mechanical performance; and risk management assessment. Evaluation methods were conducted to FDA-recognized standards where applicable.

- Data from these tests demonstrated equivalence and support the indications for use.

In summary, all necessary testing has been performed and the results support the conclusion that **EzLymph** and **EzLymph M** is substantially equivalent to the legally marketed predicate, Hydroven, based on both (a) comparison of intended use, materials, technology, and design and (b) testing to FDA-recognized standards, and the device thus does not raise any concerns of safety or effectiveness.

Based on the information contained within this submission, the applicant concludes that **EzLymph** and **EzLymph M** is substantially equivalent to the identified predicate device and warrants clearance for marketing activities.