January 29, 2020

Eezcare Medical Corp
℅ John Gillespy
President
FDA 510K Consultants, LLC
1100 Del Lago Cir, STE 104
Palm Beach Gardens, Florida 33410

Re: K191937
Trade/Device Name: Ezvena IPC, Ezvena SQS
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: December 20, 2019
Received: December 30, 2019

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)*
K191937

Device Name
EzVena IPC, EzVena SQS

Indications for Use *(Describe)*

To apply intermittent pneumatic compression to the lower limbs to help prevent deep vein thrombosis.

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.

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Section 5 – 510(k) Summary

1. 510(k) Submitter:

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3. Date of Submission: July 8, 2019

4. 510(k) Preparer:

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5. Device Classification:

Trade name:	EzVena IPC, EzVena SQS
Common name:	DVT Pump System
Device:	Sleeve, Limb, Compressible
Class:	II
Product Code:	JOW

6. Predicate:

Applicant:	Getinge (Suzhou) Co, Ltd
Device:	Flowtron ACS900
510(k) Number:	K143438

7. Device Description… EzVena IPC and EzVena SQS ("EzVena") is a deep vein thrombosis (DVT) pump system intended for performing non-invasive, intermittent compression of the lower limbs (see Figure 1).

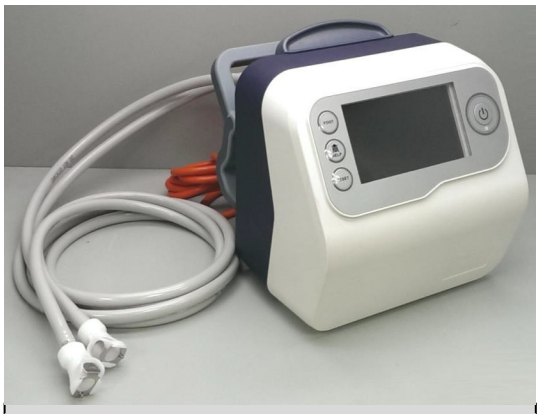


Figure 1 – EzVena Pump and Air Hoses (IPC)

The system is used to squeeze blood from the deep veins, which displaces proximally. On deflation of the cuff, the veins refill, and the intermittent nature of the system ensures periodic flow of blood through the deep veins, helping to prevent venous stasis and the formation of blood clots. The basic technology has proven effective across many scientific studies since its introduction in the 1970s.

System components include a mains-powered, pneumatic pump with touch-input control panel

and microprocessor circuit; connecting air hoses; and foot, calf, and calf/thigh garments, or cuffs. The pump intermittently releases compressed air through the tubing into inflating and deflating bladders within cuffs that are wrapped separately around the patient's left and right lower limbs.

Compression is uniform in the IPC model and graded sequential in the SQS model (see Table 1). The system alternates between left and right cuffs in EzVena IPC and inflates both garments simultaneously in EzVena SQS.

Table 1 - Uniform Vs Sequential Compression

Site of Compression	EzVena IPC	EzVena SQS
Foot	Uniform (1 Bladder)	Uniform (1 Bladder)
Calf	Uniform (1 Bladder)	Sequential (3 Bladders)
Calf/Thigh	Uniform (1 Bladder)	Sequential (3 Bladders)

Graded sequential compression (in SQS) is accomplished through the use of three bladders in calf and calf/thigh garments (by contrast, IPC cuffs and all foot garments contain but one bladder) (see Table 2). The distal bladder is inflated first, and at the highest pressure; then the central and proximal bladders are inflated in turn at stepped-down pressures. In case of power failure, the pump has battery backup.

Table 2 - Compression Differentiation

Factor	EzVena IPC	EzVena SQS
Site of Compression	Foot, Calf, Calf/Thigh	Foot, Calf, Calf/Thigh
Type of Compression	Uniform	Graded Sequential
Extent of Compression	Noncircumferential	Noncircumferential

EzVena may be operated only by acute-care personnel authorized and trained to treat DVT. The device is intended for patients at risk for the medical condition. The system is portable, and it includes a bed mount for secure placement at the foot of the patient's bed. The garments, which come in three sizes (S/M/L), contact the patient.

The pump and air hoses are reusable and cleaned before each use. The garments are for patient single use.

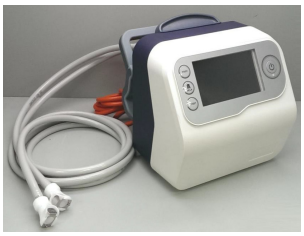
8. Mechanism of Action… Intermittent compression of air inflates and deflates cuffs, ensuring blood flow in the deep veins.

9. Indications For Use… To apply intermittent pneumatic compression to the lower limbs to help prevent deep vein thrombosis.

   The device is intended for prescription use only.

10. Comparison To Predicate and Reference Devices… See Table 3 on the following pages.

Table 3 - Comparison Table

Characteristics	Subject Device	Predicate Device	SE Comparison
Device Name	EzVena IPC & EzVena SQS	Flowtron ACS900	NA
Manufacturer	Eezcare Medical Corp	Getinge (Suzhou) Co, Ltd	NA
510k Number	Applied For	K143438	NA
Device Photo (Pump/Air Hoses)			SE
Device Photo (Calf/Thigh Garment)			SE
Regulation #	870.5800	870.5800	SE
Product Code	JOW	JOW	SE
Common Description	DVT Pump System	DVT Pump System	SE
Indication For Use	To apply intermittent pneumatic compression to the lower limbs to help prevent deep vein thrombosis.	To help prevent deep vein thrombosis.	SE
Target Population	At risk for DVT	At risk for DVT	SE
Anatomical Site	Foot/Calf/Thigh	Foot/Calf/Thigh	SE
Rx/OTC/Both	Rx Only	Rx Only	SE
Physical Characteristics--Overall			
System Description	Portable DVT pump, connecting L&R air hoses, & compressible limb sleeves (garments or cuffs)	Portable DVT pump, connecting L&R air hoses, & compressible limb sleeves (garments or cuffs)	SE
Design Concept	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	Foot, Calf, Calf/Thigh	Foot, Calf, Calf/Thigh	SE
Garment Sizes	IPC--Foot (Univ/L), Calf (S/M/L), Calf/Thigh (S/M/L); SQS--Foot (Univ/L), Calf (S/M/L), Calf/Thigh (S/M/L)	Uniform--Foot (Reg, L), Calf (Std, L), Calf/Thigh (Std, L, XL); Sequential--Calf (Reg, L, XL), Thigh (Reg), Calf/Thigh (L)	SE--Both devices offer uniform compression in single-bladder garments designed for foot, calf, and thigh; both also offer sequential compression in

Number of Air Chambers (Bladders)	IPC--1 (foot, calf, calf/thigh); SQS--1 (foot), 3 (calf, calf/thigh)	Uniform--1 (foot, calf, calf/thigh); Sequential--3 (calf, calf/thigh)	triple-bladder garments for calf and thigh.
Compression--Uniform	All 1-chamber garments (IPC + SQS foot)	All 1-chamber garments (Uniform)	
Compression--Sequential	All 3-chamber garments (SQS calf + thigh), with sequence from distal to proximal bladders	All 3-chamber garments (sequential), with sequence from distal to proximal bladders	
Compression Sequence (each cycle)	IPC--Inflate L&R alternating (30 sec each, 60 total), uniform compression; SQS--Inflate L&R together (60 sec total), sequential compression from bottom up	Inflate L&R alternating (foot 30 sec each, 60 total; calf or calf/thigh 60 sec each, 120 total; foot+calf or calf/thigh, 30 sec foot 2X then 60 sec calf or calf/thigh, 120 total)	SE--Both provide alternating L&R inflation for 1 or 2 minutes per complete cycle. Subject also compresses both L&R at same time for sequential; difference does not raise new issue of S&E.
Cycle Length	60 sec	60 sec (foot) or 120 sec (calf or calf/thigh)	
Mode of Operation	Continuous	Continuous	SE
Pressure Range	Foot--130±5mmHg; Calf/Thigh--Uniform 40±5mmHg, Sequential 45/40/30±5mmHg	Foot--130±10mmHg; Calf/Thigh--Uniform 40±5mmHg, Sequential 45±5mmHg	SE--Subject steps pressure down during sequential; difference not raise new issue of S&E (and in fact is considered preferable method).

Physical Characteristics--DVT Pump

Dimensions (mm)	190L x 203W x 194H	230L x 228W x 190H	SE--minor difference
Weight	2.5Kg (5.5lb)	4.1Kg (9.0lb)	SE--minor difference
Energy Source (Mains)	100~240V (60/50Hz)	100~230V (60/50Hz)	SE--minor difference
Energy Consumption	IPC: <18W; SQS: <23W	15W	SE--minor difference
Battery	Li-ion 2600mAh, 14.8V	NiMH 4000mAh, 13.8V	SE--Battery passed ES testing
Ingress Protection	IP22	IP23 (IEC 529)	SE--minor difference
Control Panel	TFT-LCD 4.3" color; 3.3V; 480 RGB x 272 dots	LCD 3" black; 70 x 35 dots	SE--minor difference
Integrated Bed Mount	Yes	Yes	SE
Garment Material (Patient Contact)	Nylon brush fabric	Polyester knit-blush with TPU laminated + PU foam	SE--Garment 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

S&E Testing

Biocompatibility (Garment)	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	Not provided	SE (tested to recog std)
Software Validation	SW V&V; IEC 62304:2006; EN 62366:2008	Not provided	SE (tested to recog std)
Risk Management	ISO 14971:2007	Not provided	SE (tested to recog std)
Electrical Safety	IEC 60601-1:2012	AAMI/ANSI ES60601-1:2005/R:2012 + A1:2012	SE (tested to recog std)
EMC	IEC 60601-1-2:2014	IEC 60601-1-2:2007	SE (tested to recog std)
Mechanical Safety	Pump SW/HW functionality; Garments pressure cyclic test	Pump SW/HW function-ality; Garments pressure cyclic test	SE
Reprocessing	Pump & Air Hose--clean before each use; Garment--single patient use (discarded)	Pump & Air Hose--clean before each use; Garment--single patient use (discarded)	SE

Summary of Similarities and Differences

The subject and predicate devices share the same:

- **Intended use** – apply intermittent pneumatic compression to lower limbs
- **Indications for use** – to help prevent deep vein thrombosis (DVT)
- **System design** – portable pump, air hoses, compression garments
- **Garment styles** – foot, calf, and thigh
- **Compression methods** – uniform and sequential
- **# of air chambers** – 1 (uniform compression) and 3 (sequential compression)
- **Energy sources** – mains power and battery backup
- **Materials** – ABS plastic (pump case) and biocompatible fabric (garments)
- **Reusability** – of pump and air tubing, while garments are for single-patient use

Tables 4 and 5 highlight the similarities in compression methods and other factors:

Table 4 - Uniform Vs Sequential Compression

Site of Compression	EzVena IPC & ACS900 Uniform Mode	EzVena SQS & ACS900 Sequential Mode
Foot	Uniform (1 Bladder)	Uniform (1 Bladder)
Calf	Uniform (1 Bladder)	Sequential (3 Bladders)
Calf/Thigh	Uniform (2 Bladders)	Sequential (3 Bladders)

Table 5 - Compression Differentiation

Factor	EzVena IPC & ACS900 Uniform Mode	EzVena SQS & ACS900 Sequential Mode
Site of Compression	Foot, Calf, Calf/Thigh	Foot, Calf, Calf/Thigh
Type of Compression	Uniform	Sequential
Extent of Compression	Noncircumferential	Noncircumferential

Minor differences between EzVena (subject) and Flowtron ACS900 (predicate) include:

- Compression cycle lengths – both offer 60-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.
- Pressure ranges – both increase bladder air pressure to 130 mmHg for foot treatment, 40mmHg for uniform compression of calf and thigh, and start at 45mmHg for sequential compression of calf and thigh; the subject then steps down sequential pressure for calf or thigh to 40 and 35 mmHg in the second and third bladders, respectively (while the predicate continues to reach 45mmHg in the second and third bladders). Both DVT treatment options—continuous 45 mmHg and step-down to 35mmHg—are common in the industry.
- Compression sequence – both devices alternatively inflate left and right cuffs during uniform compression treatments; the predicate continues to inflate left and right on a rotating basis for sequential compression, while the subject device chooses to inflate both sides in tandem. Either option is common in the industry.

None of the differences noted above raise new issues of safety and effectiveness.

11. Non-Clinical Testing… EzVena passed the following non-clinical tests, all of which were performed to current FDA-recognized standards, except as noted:
    - Biocompatibility… ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010
    - Electrical Safety… IEC 60601-1:2012
    - EMC… IEC 60601-1-2:2014
    - Usability Engineering… EN 62366-1:2008 (not to recognized standard)
    - Software Life Cycle… IEC 62304:2006
    - Risk Management… ISO 14971:2007
    - Symbols Used With Labels… ISO 15223-1:2012

    Clinical testing was not deemed necessary.

12. Patient-Contacting Materials… The only EzVena component that comes into contact with patients is the compression garment fabric which covers the patient's lower limbs. The garment material is polyester knit-blush with thermoplastic polyurethane (TPU) laminated + polyurethane foam.

According to ISO 10993-1, the garment is a surface device in contact with intact skin. Biological evaluation was performed in accordance with ISO 10993-1:2009 and FDA's guidance document, "Use of International Standard ISO 10993" (2016), and test results showed the material is biocompatible.

13. Software Verification and Validation… Software verification and validation testing were conducted in line with the requirements of FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (2005). The software for this device was considered as a "moderate level of concern" and software verification and validation reports have been included in this submission.

14. Cybersecurity… EzVena 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).

15. Substantial Equivalence… Many of the features and technical characteristics of EzVena IPC and EzVena SQS are identical to those of the Flowtron ACS900 predicate device, and where there are differences, such differences do not raise new issues of safety and effectiveness and do not have an impact on the safety or effectiveness of the subject device.

    EzVena IPC and EzVena SQS 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 biocompatibility, electrical safety, EMC, usability engineering, and mechanical performance; software verification and validation and life cycle documentation; and risk management assessment. Evaluation methods were conducted to FDA-recognized standards.
    - 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 EzVena IPC and EzVena SQS is substantially equivalent to the legally marketed predicate, Flowtron ACS900, 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 new concerns of safety or effectiveness.

Based on the information contained within this submission, it is concluded that EzVena IPC and EzVena SQS is substantially equivalent to the identified predicate device and warrants clearance for marketing activities.