May 10, 2018

Pegasus Medical Supply, Inc.
Pao-Ming Shih
General Manager
No. 27-1, Ln. 473, Sec. 2, Hezun N. Rd., Zhongli City
Taoyuan County, 32060 Tw

Re: K173012
Trade/Device Name: ANGIO-PRESS LITE DVT Compression Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 17, 2018
Received: April 18, 2018

Dear Pao-Ming Shih:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173012

Device Name
ANGIO-PRESS LITE DVT Compression Device

Indications for Use *(Describe)*
The Pegasus Medical Supply Inc. ANGIO-PRESS LITE DVT Compression Device is intended to increase venous blood flow in patients in order 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.

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

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510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: May 9, 2018

5.3 Submitter:

Address:	Pegasus Medical Supply, Inc. No.27-1, Ln. 473, Sec. 2, Hezun N. Rd., Zhongli City, Taoyuan County 32060, Taiwan (R.O.C.)
Phone:	+886-3-2753341
Fax:	+886-3-4616802
Contact:	PAO-MING SHIH (borisshih@pegasus-pms.com)

5.4 Identification of the Device:

Proprietary/Trade name:	ANGIO-PRESS LITE DVT Compression Device
Classification Product Code:	JOW
Regulation Number:	870.5800
Regulation Description:	Compressible limb sleeve
Review Panel:	Cardiovascular
Device Class:	II

5.5 Identification of the Predicate Device:

Predicate Device Name:	ANGIO-PRESS DVT Compression Device Model Name: IPCS
Manufacturer:	Pegasus Medical Supply, Inc.
Classification Product Code:	JOW
Regulation number:	870.5800
Device Class:	II
510(k) Number:	K143202

5.6 Intended Use/ Indications for Use of the Device

The Pegasus Medical Supply Inc. ANGIO-PRESS LITE DVT Compression Device is intended to increase venous blood flow in patients in order to help prevent deep vein thrombosis.

5.7 Device Description

The ANGIO-PRESS LITE DVT Compression Device is a non-invasive intermittent pneumatic compression system that aids in prevention and reduction in incidence of deep vein thrombosis (DVT).

The system consists of a pump and soft pliable compression single patient use garments for leg or foot compression. The pump supplies compression on a pre-set inflation pressure of 40mmHg for calf and thigh compression, and 80mmHg for foot compression. Pressure in the garments is transferred to the extremities, augmenting venous blood flow, thus reducing stasis.

5.8 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, ANGIO-PRESS LITE DVT Compression Device.

- Biocompatibility
- Software Validation
- Electromagnetic compatibility and electrical safety
- Reliability
- Performance
- Usability

All the test results demonstrate ANGIO-PRESS LITE DVT Compression Device meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

5.9 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.10 Substantial Equivalence Determination

The ANGIO-PRESS LITE DVT Compression Device submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared ANGIO-PRESS DVT Compression Device Model Name: IPCS (K143202). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary Name	ANGIO-PRESS LITE DVT Compression Device	ANGIO-PRESS DVT Compression Device	N/A
Model Name	ANGIO-PRESS LITE	IPCS	
510(k) No.	(to be assigned)	K143202	
Intended Use	The Pegasus Medical Supply Inc. ANGIO-PRESS LITE DVT Compression Device is intended to increase venous blood flow in patients in order to help prevent deep vein thrombosis.	The Pegasus Medical Supply Inc. ANGIO-PRESS IPCS Deep Vein Thrombosis (DVT) Compression Devices is intended to increase venous blood flow in patients in order to help prevent deep vein thrombosis.	Same
Type of use	Prescription Use	Prescription Use	Same
For Control Unit (Pump)			
Size (L x W x H)	26 x 10.5 x 16 cm	31.5 x 11 x 19.5 cm (12.6” x 4.3” x 7.7”)	Different but does not impact safety and effectiveness of subject device
Weight	2.5 Kg	3.1 Kg	Different but does

			not impact safety and effectiveness of subject device
Pressure Range	Calf/Thigh: 40 mmHg Foot: 80 mmHg	Calf/Thigh: 40 mmHg Foot: 80 mmHg	Same
Input Rating	AC 110-120V, 60Hz	AC 100-240V, 50/60Hz	Different but does not impact safety and effectiveness of subject device
Fuse Rating	T1AL 250V	1A/250V	Different but does not impact safety and effectiveness of subject device
IEC Classification	Class II, Type BF Not AP or AGP type	Class I Type BF Not AP or APG type	Different but does not impact safety and effectiveness of subject device
Ingress of Water Protection	IP21	N/A	Different but does not impact safety and effectiveness of subject device
Operation Humidity	30% to 75% non-condensing	30 - 75%	Same
Operation Temperature	15°C - 40°C	15°C - 35°C	Different but does not impact safety and effectiveness of subject device
Operation Atmospheric Pressure Range	700 hPa to 1060 hPa	700 hPa to 1060 hPa	Same
Mode of Operation	Continuous	Continuous	Same
Applied Part	Garment and Air Tubing	Garment and Air Hose	Same
Applied Mode of	Intermittent	Intermittent	Same

Pressure					
Inflation time per chamber	12 seconds		12 seconds		Same
Deflation time per chamber	48 seconds		48 seconds		Same
Airflow	≧ 6.0 L/min		≧ 6.0 L/min		Same
Software	w/o Timer and Pressure display w/o Reset Timer function		w/ Timer and Pressure display w/ Reset Timer function		Different but does not impact safety and effectiveness of subject device
Control Panel					
For Applied Part					
Calf Garments (For calf circumference)	Small	Up to 14”	Extra Small (XS)	35 cm	Different but does not impact safety and effectiveness of subject device
	Medium	Up to 18”	Small (S)	43 cm	
	Large	Up to 24”	Medium (M)	48 cm	
	Bariatric	Up to 32”	Bariatric (B)	81 cm	
Thigh Garments (For thigh circumference)	Medium	Up to 29”	Medium (M)	71 cm	Different but does not impact safety and effectiveness of subject device
	Large	Up to 36”	Large (L)	89 cm	
	Bariatric	Up to 42”			
Foot Garments (For US men’s size)	Standard	Up to 13	Regular (U)	Size 7 – 9	Different but does not impact safety and effectiveness of subject device
	Large	Over 13	Large (L)	Size 9 - 11	
Air Tubing / Air Hose	Replacement tubing, 60” and 120”		Air hose extension of 1.5, 3, and 4.5 metres		Different but does not impact safety and effectiveness of subject device

5.11 Similarity and Difference

The ANGIO-PRESS LITE DVT Compression Device has been compared with "ANGIO-PRESS DVT Compression Device Model Name: IPCS". The subject device has same intended use, principle of operation and similar technological characteristics as the predicate device. Although there are some specifications that are different between two devices, the performance test has been completed to demonstrate that the differences between these parameters would not impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore, the difference between the subject device and the predicate device did not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use, safety and performance claims.

5.12 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that the ANGIO-PRESS LITE DVT Compression Device is substantially equivalent to the predicate device.