DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 16, 2015

PulseFlow Technologies
% Diane Horwitz
Regulatory Consultant
Mandell Horwitz Consultants
2995 Steven Martin Dr.
Fairfax, Virginia 22031

Re: K150806
Trade/Device Name: PulseFlowDF
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: November 11, 2015
Received: November 13, 2015

Dear Diane Horwitz:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150806

Device Name
PulseFlowDF™

Indications for Use *(Describe)*
The PulseFlowDF™ is designed to enhance blood circulation in the venules and arterioles in patients with diabetic foot ulcers of the lower extremities.

PulseFlowDF is intended for patients in the home who would benefit from increased blood flow to:

- Treat and assist healing of cutaneous ulceration (wounds)
- Reduce wound healing time
- Enhance arterial circulation (blood flow)
- Prevent venous stasis (slowing of blood flow)
- Reduce compartmental pressures
- Reduce edema (swelling)
- Reduce post-operative pain and swelling
- Reduce the need for anticoagulant medications (medications that thin the blood) and
- Prevent Deep Venous Thrombosis (DVT) (blood clots in the deep veins).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Submitter's information	PulseFlow Technologies Midshires House, Midshires Business Park, Smeaton Close Aylesbury, UK HP19 8HL Contact Name: Les Lindsay Telephone: +44 1296 678596
Device/ classification name	Device Name: **PulseFlowDF, K150806** 510(k) Number: K150806 Device Class: Class II Classification Number: 21 CFR 870.5800 Classification Name: Compressible limb sleeve Product Code: JOW Classification Panel: Cardiovascular
Predicate Device	Cowboy XV, marketed as PlexiPulse, K981311
Device Description	PulseFlowDF is an off-loading boot with a built in air bladder in the insole for intermittent plantar compression therapy. One active boot and one matched height inactive boot is provided. PulseFlowDF is designed to protect a diabetic wound during healing by (1) stimulating blood flow to the wound (and throughout the foot and leg) by means of cyclic inflation of an air bladder under the arch of the foot (primary action), (2) providing a protective cover for the wound which is bandaged and shielded inside the boot) and (3) stabilizing the foot and lower leg with an "off-loading design" that holds the foot and lower leg in a fixed position to reduce pressure on the sole of the foot (secondary action). PulseFlowDF allows the user to walk and move while wearing the boot. PulseFlowDF is worn for up to 10 to 15 hours per day for 12 weeks, after which time it can be converted to standard footwear.
Intended Use	The PulseFlowDF is designed to enhance blood circulation in the venules and arterioles in patients with diabetic foot ulcers of the lower extremities. PulseFlowDF is intended for patients in the home who would benefit from increased blood flow to: • Treat and assist healing of cutaneous ulceration (wounds) • Reduce wound healing time • Enhance arterial circulation (blood flow) • Prevent venous stasis (slowing of blood flow) • Reduce compartmental pressures • Reduce edema (swelling) • Reduce post-operative pain and swelling • Reduce the need for anticoagulant medications (medications that thin the blood) and • Prevent Deep Venous Thrombosis (DVT) (blood clots in the deep veins).

SUBSTANTIAL EQUIVALENCE COMPARISON

	NEW DEVICE PulseFlowDF, K150806	PREDICATE DEVICE PlexiPulse, K981311	Same or Different
Intended Use	See above	Identical	Same
Device Description	Foot and lower leg held in position using a shin support and offloading boot to redistribute pressure across the foot; boot contains inbuilt air bladder and inflation mechanism for pressure against plantar venous plexus	Pump connected through tubing to inflatable foot wraps	Similar. Foot is compressed with inflatable bladder.
Mode of Action	Generates pneumatic pressure using an internal pump and promotes blood flow via intermittent plantar compression. Redistributes pressure evenly across sole of foot during gait cycle to avoid pressure hot spots that leading to tissue damage/ delayed wound healing	Generates pneumatic pressure using an external pump and promotes blood flow via intermittent plantar compression	Same and Different. The new device has the same active pumping mechanism for the same purpose. The new device has the additional functionality of being an off-loading boot that helps re-distribute pressure on the sole of the foot. The new device allows the user to be mobile during treatment. Differences have been shown to result in increased blood flow to the foot and to be usable by the subject.
Components	Boot, Off-loader, Motor, Battery charger, Mini-USB cable (Professional Use), CD with Download program (Professional Use)	PlexiPulse pump, foot wrap, Tubing and tube connector, Power cord	Different. Components of new device have been demonstrated to achieve their intended purpose.
Energy Source	Lithium Battery	Electrical (A/C Power Supply) 110 VAC, 60 Hz, 0.25 A	Different. Power source has been demonstrated to achieve its intended purpose.
Software Controlled	Firmware for compliance data download and to stop pump after 1000 treatment hours	Unknown extent of software regulation	Similar; both have been V&V tested.
Size of Unit	Boot-shaped and sized	Inflatable wrap around foot Pump 12” x Depth 7” x Height 11”	Different. Boot shape allows subject to be mobile.
Max. Pressure Generation	160mm Hg Fixed pressure	160 ±15 mm Hg (140 to 180 mmHg), Adjustable	Same
Duration of Pulse	Inflation cycle every 20sec, duration 2 sec, Fixed duration	Inflation cycle every 20sec, duration 2 sec, Adjustable (20 to 60 sec)	Same

Performance Data	Performance testing was conducted to ensure that user requirements and specifications were met, and to ensure that any differences between PulseFlowDF and the predicate would not affect safety or effectiveness. Performance testing included the following: ***Electrical Safety Testing***: Electrical safety was tested according to IEC 60601-1. Test results were a pass. ***Electromagnetic Safety***: PulseFlowDF was tested to the requirements of International Electromagnetic Compatibility standards, with respect to radio frequency emissions and radio frequency susceptibility. Test results were a pass. ***Manufacturing validation including pressure relief valve testing:*** In-process manufacturing validation is performed to ensure that all components function as required. ***Lithium Battery testing***: The 7.4V nominal voltage rechargeable lithium battery pack, 950mAh rated capacity, is compliant with the requirements of IEC 62133: 2012. ***Pressure mapping testing***: Verification of the off-loading properties of PulseFlowDF was demonstrated in bench testing. ***Bench Performance testing:*** Bench performance testing was performed to verify that the PulseFlow device disables at 1000 hours, that the inflation and deflation specifications are achieved, and that the inflation pressure specifications are reliably achieved. Bench testing was conducted to demonstrate that the pressure relief valve functions as intended and that the bladder structure and material can withstand a sudden large force being exerted on the bladder. ***Simulated Use testing***: Bench performance testing was performed to validate that the integrity of the mechanical components can withstand the anticipated forces and pressure throughout the 12-week operating period for a simulated 400lb body weight without failure of the mechanical components. ***Software Verification and Validation***: V&V testing was performed for the firmware in PulseFlowDF, which is used to monitor compliance with wear time. ***Summative Usability Testing***: A summative usability test was performed in ten (10) diabetic patients under treatment for active or healed diabetic foot ulcers and two (2) healthcare professionals. The usability validation study revealed that no safety issues occurred while using PulseFlowDF, performance of essential tasks was demonstrated, particularly with face-to-face training in suitable patients, as planned. ***Measurement of Blood Flow***: In a validation study with eight (8) volunteer subjects, venous blood flow in the calf and microvascular perfusion of the foot were statistically significantly improved during use of PulseFlowDF, as measured using a Near-Infrared Spectroscopic technique (blood flow in the calf) and a Doppler flowmeter (microvascular perfusion of the foot), confirming the efficacy of PulseFlowDF's intermittent compression to improve blood flow
Conclusions	Based on the documentation presented in this 510(k) it has been demonstrated that PulseFlowDF is substantially equivalent to the predicate device for its intended use.

Date Summary Prepared: December 10, 2015