September 3, 2021

Huntleigh Healthcare Ltd
Steve Monks
QRE Director
35 Portmanmoor Road
Cardiff, CF24 5HN
United Kingdom

Re: K211200
Trade/Device Name: WoundExpress
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: July 30, 2021
Received: August 5, 2021

Dear Steve Monks:

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,

for Nicole Gillette
Acting 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K211200

Device Name
WoundExpress

Indications for Use *(Describe)*
WoundExpress aids in the treatment of the following clinical conditions:
- Chronic wounds including leg ulcers (venous leg ulcers and mixed aetiology leg ulcers)
- The management of lower limb pain

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary
# WoundExpress


| | |
|---|---|
| Name & Address: | Huntleigh Healthcare Limited<br>Unit 35, Portmanmoor Road<br>Cardiff<br>CF24 5HN<br>United Kingdom |
| Telephone: | +44 (0)2920 485885 |
| Fax: | +44 (0)2920 492520 |
| Prepared: | 14th April 2021 |
| Contact: | Steve Monks |

## 5.1 Device Information

| | |
|---|---|
| Device Trade Name: | WoundExpress |
| Regulation Name: | Compressible Limb Sleeve |
| Regulation Number: | 21 CFR 870.5800 |
| Product Code: | JOW |
| Device Classification Name: | Sleeve, Limb, Compressible |
| Regulatory Class: | II |
| Review Panel: | Cardiovascular |

## 5.2 Predicate Device Information

| | |
|---|---|
| Predicate Devices: | ActiveCare+SFT System (K110159) manufactured by Medical Compression Systems (DBN) Ltd.<br>VenaPro Vascular Therapy System (K193020) manufactured by Innovamed Health, LLC. |
| Regulation Name: | Compressible Limb Sleeve |
| Regulation Number: | 21 CFR 870.5800 |
| Product Code: | JOW |
| Device Classification Name: | Sleeve, Limb, Compressible |
| Regulatory Class: | II |
| Review Panel: | Cardiovascular |
| | The predicate devices have not been subject to a design-related recall. |

## 5.3 Indications for Use

Indications for Use:

WoundExpress aids in the treatment of the following clinical conditions:

- Chronic wounds including leg ulcers (venous leg ulcers and mixed aetiology leg ulcers)
- The management of lower limb pain.

## 5.4 Description

Description :

The WoundExpress Therapy Device is an intermittent pneumatic compression system consisting of a pump unit and a thigh garment, interconnected by a detachable three chamber tube set. It is a non-invasive mechanical system designed to enhance blood and lymph flow as a therapy to manage the clinical condition listed above.

The pump is a portable, ac mains powered device, that produces a pre-set pneumatic therapy cycle delivered through a 3 port output connector, which is connected to a three chamber garment that is applied to the patient thigh.

The pump operates on a 4 minute automatically timed gradient pressure sequence, consisting of a 2 minute venous emptying phase and a 2 minute rest phase. The venous emptying phase consists of six 20 second compression cycles, while no compression takes place during the rest phase. Each 20 second compression cycle is characterised by overlapping synchronous inflations and deflations of the distal (lower), central (middle) and proximal (upper) chambers.

Models

Wound Express Pump: WE100P

Wound Express Garment: WE100G

## 5.5 Comparison of Technological Characteristics with Predicate Device

Intermittent Pneumatic Compression is the technological principle for both the subject and predicate device. The system comprises of a pump and garment.

| Technological Element | ActiveCare+SFT System (K110159) | VenoPro Vascular Therapy System (K193020) | WoundExpress |
|---|---|---|---|
| Basis of operation | Enhances blood flow using intermittent pneumatic compression application (inflation followed by deflation) | Aids venous return by using cyclic intermittent pneumatic compression application (inflation followed by deflation) | Aids venous return by using cyclic intermittent pneumatic compression application (inflation followed by deflation) |
| Application | Non-invasive / external | Non-invasive / external | Non-invasive / external |
| Number of Chambers in garment | 3 | 1 | 3 |
| Cycle Time | 8 seconds compression followed by 36-56 seconds of rest. | 10 seconds compression followed by 50 seconds of rest. | 20 second compression cycles (x6), followed by 120 seconds rest. |
| Material | Brushed Nylon | PVC coated with soft, non-latex woven | Brushed Loop Woven Nylon |

| | | | |
|---|---|---|---|
| | | medical fabric. | Polyurethane Foam<br>100% Nylon textured binding<br>Polyurethane Film |
| Pressure range | 50mmHg ± 10% when applied to the thigh.<br>130mmHg ± 10% when applied to the foot. | Fixed at 50mmHg | Fixed at 60mmHg ± 5mmHg |
| Power Source | 7.2 VDC (NiMH rechargeable batteries) | 3.7v rechargeable battery | Mains powered |
| Size | 135 x 135 x 60mm | 131 x 66 x 37mm | 270 x 130 x 150mm |
| Indicators | ON/OFF Indicator – Green light<br>Attention Indicator – Airway obstruction / air leakage / low battery / no treatment mode | Blue & tri-colour indicator.<br>Blue LED – leak or low pressure alarm<br>Tri-colour LED – On, low battery, charging, charge completed. | Power Status, Rest and Off / Normal Operating Range / Error Refer to Service |

Review of differences:

- Number of chambers – The subject device has 3 chambers along with the ActiveCare+SFT predicate. All devices use intermittent pneumatic compression to inflate and deflate the chambers to help stimulate blood flow. This difference does not affect safety or efficacy.
- Cycle time – The subject device operates on 20 second compression cycles (x6), followed by 120 seconds rest, whereas the predicates operate on a 10 second compression followed by 50 seconds rest and 8 seconds compression followed by 36-56 seconds of rest. All include a compression stage and a rest period. For the subject device, the cycle time has been optimised specifically for leg ulcers, whereas the predicate device has a much broader indications for use. This difference does not affect safety or efficacy.
- Garment Material – The difference in garment material does not affect, safety or effectiveness of the subject device. The materials used in the subject device are identical to materials used in an already marketed device (K172103). This difference is insignificant.
- Pressure Range – The pressure for the subject device is fixed at 60mmHg, whereas the predicates are fixed at 50mmHg (when applied to the thigh for the ActiveCare+SFT). The subject device's pressure is only slightly higher and has been tested to prove its

safety and effectiveness. This difference is insignificant.

- Power Source – The subject device is mains operated, whereas the predicate devices are battery operated. The subject device is compliant to the electrical safety standard IEC 60601-1. This difference does not affect safety or effectiveness.
- Size– The subject device is bigger than the predicate devices. This difference has no bearing on functionality, safety or efficacy of the subject device. This difference is insignificant.
- Indicators – The subject device uses a pressure gauge display whereas the predicate devices used LED lights. This difference does not affect safety of effectiveness.

## 5.6 Substantial Equivalence

| | |
|---|---|
| Substantial Equivalence: | The WoundExpress is substantially equivalent to the cleared predicate devices ActiveCare+SFT System and VenaPro Vascular Therapy System. The WoundExpress has equivalent performance to the ActiveCare+SFT System and VenaPro Vascular Therapy System. |

## 5.7 Performance Data

Testing to demonstrate substantial equivalence included:

| Testing Conducted | Discussion |
|---|---|
| Biocompatibility Testing<br>-Cytotoxicity<br>-Sensitization<br>-Irritation | The biocompatibility evaluation of the device was conducted in accordance with *ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.* The Wound Express garments are surface devices (intact skin contact) designed to be used on patients for prolonged duration (cumulative duration of 24 hours to 30 days). |
| Electronic Hardware Testing | Testing provides verification of the Wound Express's two PCB assemblies including logic supply (and with ripple voltage), reset pulse, operating frequency, min |

| | |
|---|---|
| | ON-time, optp-triac drive, zero-crossing voltage, triac switch off, optical sensor and hardware timer. |
| Mechanical Testing | Testing provides verification of mechanical performance including general, physical, environment, packaging and durability.<br><br>Testing also confirmed Basic Safety and Essential Performance are maintained in accordance with IEC 60601-1-11:2015. |
| Functional Testing | Testing provides verification that the Wound Express pump and garment system works as intended as fulfils the requirements of the technical specifications. |
| Performance Testing | The WoundExpress has undergone a validation study to ensure the device can achieve its intended use. The validation concluded the device is fit for purpose and the clinical benefits of the device outweighs the overall residual risk. |
| Electrical Safety Testing | Electrical safety testing was conducted on the product by a third party laboratory, UL. Testing confirms device complies with IEC 60601-1:2005 + A1:2012. |
| EMC Testing | EMC testing was conducted on the product by a third party laboratory. Testing confirms device complies with EN 60601-1-2:2015. |
| Environmental Performance Testing | Testing provides verification of the non-operational shock and vibration. |

## 5.8 Technologies Summary

Technologies The WoundExpress uses similar technology to the

Summary:

predicate devices; ActiveCare+SFT System and VenaPro Vascular Therapy System. All aid venous return by using cyclic intermittent pneumatic compression application (inflation followed by deflation).

The application of the WoundExpress is the same as the ActiveCare+SFT System predicate device as the garments for both can be applied to the thigh. The subject device is indicated for adults with chronic wounds including leg ulcers and therefore the garment is applied to the thigh, away from the wound site making it more comfortable and easily tolerated by the patient.

The WoundExpress subject device delivers pressure fixed at 60mmHg ±5mmHg, which is adjusted and calibrated at the factory, to simplify the operation by the patient. This pressure is only slightly higher than the predicate devices.

The WoundExpress cycle time is 20 second compression cycles (x6), followed by 120 seconds rest. This cycle time is optimised to deliver the best treatment therapy for chronic wounds including leg ulcers.

## 5.9 Conclusion

Conclusion:

The data detailed within this submission demonstrates that the WoundExpress is as safe and effective as the predicate devices ActiveCare+SFT System and VenaPro Vascular Therapy System and performs as well as the predicate devices identified in this summary, which is currently marketed for the same intended use. The device hardware, mechanical and functional verification demonstrates that it should perform as intended in the specified user conditions.