510(k) Summary
807.92(c)

OCT 2 6 2010

SPONSOR **807.92(a)(1)**

Company Name:	AUGDVT LLC
Company Address	723 South Casino Center Blvd., 2nd Floor Las Vegas, NV 89101-6716
Telephone:	760-744-2882
Fax:	760-744-2993
Contact Person:	Jeffrey Michaels

Summary Preparation Date: September 14, 2010

DEVICE NAME **807.92(a)(2)**

Trade Name:	AugEase™
Common/Usual Name:	Vascular augmentation device
Classification Name:	Sleeve, Limb, Compressible
Regulation Number:	870.8500
Product Code:	JOW
Device Class:	II
Panel:	Cardiovascular

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
ACI Medical, Inc.	Venapulse Models VP-25 & VP-50	K903894

DEVICE DESCRIPTION **807.92(a)(4)**

The AugEase™ is a foot actuated augmentation device intended to be used during a vascular ultrasound exam of the extremity. It consists of a foot actuated pneumatic device that is used to rapidly inflate and deflate an air bladder cuff that has been placed around the patient limb at the appropriate location. Quickly inflating and deflating the cuff creates a waveform image that is captured by the ultrasound machine and used in the diagnosis of a variety of conditions.

DEVICE INTENDED USE **807.92(a)(5)**

The AugEase™ is a foot actuated augmentation device intended to rapidly inflate and deflate an air bladder cuff generating static, tourniquet pressure to limbs of patients undergoing vascular testing. It is indicated as an accessory to an ultrasound imaging machine with or without Doppler which may be used for:

- Distal augmentations
- Proximal augmentations
- Reflux measurements of specific venous valves
- Vein Mapping
- Locating suitable distal vessel for bypass

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

PREDICATE PRODUCT COMPARISON

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Feature	AUGEASE™ device	Venapulse Model VP 25
Intended use and claims	The AugEase™ is a foot actuated augmentation device intended to rapidly inflate and deflate an air bladder cuff generating static, tourniquet pressure to limbs of patients undergoing vascular testing. It is indicated as an accessory to an ultrasound imaging machine with or without Doppler which may be used for: • Distal augmentations • Proximal augmentations • Reflux measurements of specific venous valves • Vein Mapping • Locating suitable distal vessel for bypass Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	Vena*Pulse*® Model VP-25 generates static, tourniquet pressure to limbs of patients undergoing vascular testing. The tourniquet pressure is reached very rapidly and the tourniquet cuff is deflated very rapidly with approximately 300 millisecond rise and fall times. Inflation and deflation are controlled with a foot switch or with a manual switch. The pressure is regulated between 0 and 240mmHg. There are safety alarms to ensure safe operation. Indications For Use: • Distal augmentations • Proximal augmentations • Vein mapping • Locating suitable distal vessel for bypass • Quantification of venous

		flow • Reflux measurements of specific venous valves
510(k) Number	K101355	K903894
Classification	Compressible Limb Sleeve	Compressible Limb Sleeve
Product Code	JOW	JOW
Technological characteristics	1. MANUAL 2. PNEUMATIC 3. 0.8L MAXIMUM VOLUME 4. RAPID INFLATION CUFF 5. LARGE DIAMETER HOSE	1. ELECTRIC 2. COMPUTER AUTOMATION 3. PNEUMATIC 4. UNKNOWN MAXIMUM VOLUME 5. RAPID INFLATION CUFF 6. LARGE DIAMETER HOSE
Mode of operation	Rapid inflation and deflation Foot actuated	Rapid inflation and deflation Foot switch/manual switch
Inflation/deflation rise and fall time	0.5 seconds	300 millisecond
Pressure	0-240mm/Hg	0-240mmHg
Safety feature	1. Check Valve 1.0 psi 2. 300mm/Hg Gauge	1. Alarm
Instructions for use	yes	yes
Non-sterile	yes	yes

NONCLINICAL AND CLINICAL TEST **807.92(b)**

Product Validation Testing:

II. Burst pressure;
III. Materials testing;
- Cytotoxicity Test;
- Sensitization Test;
- Irritation and Intracutaneous Reactivity Test
- Tensile Strength Test;

IV. Method of attachment (Velcro or straps);
V. Seal Strength Comparison;
VI. Cuff Leak Testing;

SAFETY and EFFECTIVENESS

The AugEase™ Vascular is similar to the predicate device in intended use and mode of operation. The AugEase™ is a manually operated device and does not raise any new issue of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AugDVT LLC
c/o Mr. E. J. Smith
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

OCT 26 2010

Re: K101355
Trade/Device Name: AugEase™
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: September 14, 2010
Received: September 14, 2010

Dear Mr. Smith:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K101355

OCT 2 6 2010

Device Name: AugEase™

Indications for Use:

The AugEase™ is a foot actuated augmentation device intended to rapidly inflate and deflate an air bladder cuff generating static, tourniquet pressure to limbs of patients undergoing vascular testing. It is indicated as an accessory to an ultrasound imaging machine with or without Doppler which may be used for:

- Distal augmentations
- Proximal augmentations
- Reflux measurements of specific venous valves
- Vein Mapping
- Locating suitable distal vessel for bypass

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101355