**510(k) Summary**

**807.92(c)**

**SPONSOR**

**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

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**DEVICE NAME**

**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

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**PREDICATE DEVICE**

**Legally Marketed Equivalent Device**

**Company:** ACI Medical, Inc.

**Product:** Venapulse Models VP-25 & VP-50

**510(k) #:** K903894

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**DEVICE DESCRIPTION**

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

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

<table>
<thead>
<tr>
<th>Feature</th>
<th>AugEase™ device</th>
<th>Venapulse® Model VP-25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended use and claims</td>
<td>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:</td>
<td>Venapulse® 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.</td>
</tr>
<tr>
<td></td>
<td>• Distal augmentations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Proximal augmentations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reflux measurements of specific venous valves</td>
<td></td>
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<tr>
<td></td>
<td>• Vein Mapping</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Locating suitable distal vessel for bypass</td>
<td></td>
</tr>
<tr>
<td>Caution: Federal (USA) law</td>
<td>restricts this device to sale by or on the order of a physician.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Indications For Use:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Distal augmentations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Proximal augmentations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Vein mapping</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Locating suitable distal vessel for bypass</td>
<td></td>
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<tr>
<td></td>
<td>• Quantification of venous</td>
<td></td>
</tr>
<tr>
<td>Product Code</td>
<td>JOY</td>
<td>JOY</td>
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<tr>
<td>-------------</td>
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</tr>
<tr>
<td><strong>Technological characteristics</strong></td>
<td>1. MANUAL</td>
<td>1. ELECTRIC</td>
</tr>
<tr>
<td></td>
<td>2. PNEUMATIC</td>
<td>2. COMPUTER AUTOMATION</td>
</tr>
<tr>
<td></td>
<td>3. 0.8L MAXIMUM VOLUME</td>
<td>3. PNEUMATIC</td>
</tr>
<tr>
<td></td>
<td>4. RAPID INFLATION CUFF</td>
<td>4. UNKNOWN MAXIMUM VOLUME</td>
</tr>
<tr>
<td></td>
<td>5. LARGE DIAMETER HOSE</td>
<td>5. RAPID INFLATION CUFF</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. LARGE DIAMETER HOSE</td>
</tr>
<tr>
<td><strong>Mode of operation</strong></td>
<td>Rapid inflation and deflation</td>
<td>Rapid inflation and deflation</td>
</tr>
<tr>
<td></td>
<td>Foot actuated</td>
<td>Foot switch/manual switch</td>
</tr>
<tr>
<td><strong>Inflation/deflation rise and fall time</strong></td>
<td>0.5 seconds</td>
<td>300 millisecond</td>
</tr>
<tr>
<td><strong>Pressure</strong></td>
<td>0-240mm/Hg</td>
<td>0-240mmHg</td>
</tr>
<tr>
<td><strong>Safety feature</strong></td>
<td>1. Check Valve 1.0 psi</td>
<td>1. Alarm</td>
</tr>
<tr>
<td></td>
<td>2. 300mm/Hg Gauge</td>
<td></td>
</tr>
<tr>
<td><strong>Instructions for use</strong></td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Non-sterile</strong></td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

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

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/CDRHYCDRHOffices/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” (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 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,

Sr. Brain 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

Device Name: AugEase™

Indications for Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Division Sign-Off
Division of Cardiovascular Devices

510(k) Number K101355