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**Contact:**  
Todd Aldrich  
Tel 1-651-233-5948  
taldrich@biomedix.com

**FDA Grants Marketing Clearance for Peripheral Artery Disease Diagnostic Device**  
*Early Detection of Disease Can Save Lives*

**TWIN CITIES, MN - October 12, 2004** - BioMedix announced today that the U.S. Food and Drug Administration (FDA) has granted marketing clearance for the company's PADnet Lab™, a non-invasive device designed to detect peripheral artery disease (PAD) in its earliest stages. PADnet Lab™ received clearance as a 501K equivalent predicate device.

"There are more than 10 million Americans with peripheral arterial disease and most do not know it. Without proper treatment a third of these people are likely to die in the next five years due to PAD-related heart attack or stroke," said John Martin, M.D., Director, Vascular Institute, Anne Arundel Medical Center. "PADnet Lab™ will provide physicians with an easy-to-use device that can detect PAD early in disease progression and this could save lives in the long run."

The PADnet Lab™ detects blockages in arteries and the quality of blood flow using pulse volume recording and oscillometric segmental blood pressure measurement. The device is lightweight (about six pounds) and portable and includes a laptop computer and color printer on a medical grade cart. The test can be performed in 20 minutes or less. Test results are transferred to vascular specialists via a HIPAA compliant website and diagnosis and treatment recommendations are returned to the test site within 24 hours. Few PAD patients have the classic symptom of disease known as claudication or consistent pain after walking a certain distance. Most have atypical symptoms such as discomfort after walking variable distances or while at rest. In these patients, it is vital for physicians to perform a thorough pulse examination and determine the ankle-brachial index (ABI), or the ratio of blood pressures at the arm and ankle levels. However, obtaining the ABI requires the use of Doppler ultrasound, and a probe like a stethoscope to determine the return of pressure when blood flow to an artery is interrupted. This probe is difficult to master and primary care physicians are not able to obtain reimbursement for the ABI test alone.

The PADnet Lab™ eliminates use of the Doppler, and instead uses an oscillometric method, or measurement of oscillations caused by the arterial pressure pulse. It works in conjunction with a pressure cuff. The pressure cuff is applied and inflated to shut off flow in the artery. When the cuff is deflated, the device records the oscillations and assigns a systolic pressure value. Doppler ultrasound devices and devices combining Doppler and plethysmography (PVR), a method of determining blood perfusion to a limb segment have been widely available for many years, but the PADnet Lab is the first to incorporate oscillometric means of obtaining ankle pressures and the unique packaging of this technology with PVR and web tools to enable primary care physicians to link up with specialists in the communication of test results and follow-up care. "While reliable, Doppler is far more difficult to use than oscillometric means," said Will Rogers, Vice President, Clinical Services and one of the two principal inventors of PADnet Lab™.

The PADnet Lab also uses includes pulse volume recording (PVR), a form of plethysmography, in which pressure cuffs are inflated to a pressure low enough to allow blood flow but high enough to sense volume changes in the artery as the blood vessel expands and contracts.

It displays these PVR changes as a waveform, and these waveforms are helpful isolating the disease when the ABI shows an abnormal result. PADnet Lab™ will be reimbursed for approved physical signs and symptoms under existing Medicare code CPT 93923, which provides for payment of a professional and technical fee for performing and professional interpretation of the exam. "In the past, PAD was under-diagnosed and under-treated because of a lack of a sophisticated yet reliable and easy-to-use test," said Todd Aldrich, Marketing VP of BioMedix. "The approval of PADnet Lab™ will be welcomed news to physicians and the patients they treat with PAD."

### **About BioMedix**

BioMedix is the fastest growing provider of equipment and services in the market for non invasive detection of peripheral vascular disease (PVD). Unique technology also links primary care physicians and vascular surgeons in the early detection of PAD through simple web-enabled vascular testing devices, software and services. Innovative vascular lab and surgery suite management software tools also enable vascular care system providers to meet clinical and economic objectives.

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