

K960946

## 510(k) Summary

MAY - 7 1996

### Identification of the Product

**Trade Name:** EchoNet  
**Common Name:** Unknown  
**Classification Name:** Device, Digital Image Storage

**Manufacturer:** Lockheed Martin  
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**Date Prepared:** 06 March 1996

### Indications for Use:

EchoNet is software which runs on Unix workstations. EchoNet is intended to be used for storing and displaying digital images acquired by digital ultrasound imaging systems. EchoNet provides rapid network access to the imagery and patient demographic data stored on a central server. The system retrieves and stores images as unaltered computer data and as JPEG (Joint Photographic Experts Group) lossy compressed cine-loops. This dual-path storage system allows for rapid access to high quality compressed images with the original unaltered (losslessly compressed) images available on demand. EchoNet is a scalable network system designed to service customers ranging in size from small departments (with 2 or 3 users) to large hospital networks (with tens of users).

### Device Descriptions:

EchoNet is composed of the following:

**EchoNet Client:** Unix workstation which permits review and diagnosis of ultrasound imagery and demographics. This review software provides basic controls such as play/pause, image contrast/brightness and image scaling. The system is capable of displaying two types of stored imagery. High quality JPEG compressed (Q-Factor 75 compression ratio approximately 15 to 1) digital cine-loops and unaltered digital cine-loops. The JPEG images are intended for preview and preliminary assessment while the original data is always available on demand.

EchoNet Server: Unix workstation based database and image server software combined with a virtual file system. The server is a central archive for imagery and patient information. The EchoNet server may be configured with a variety of mass storage devices. These devices such as hard-disks, optical juke-box libraries and tape libraries provide on-line and archival storage of images.

### **Marketing History**

Lockheed Martin is about to begin marketing the EchoNet product. The EchoNet product, as to be marketed, is identical to the Heartlab EchoNet product described in a previous 510(k) submission with registration number **K954860**.

### **Potential Adverse Effects on Health**

The potential concerns (data handling) are controlled by Failure Mode and Effects Analysis (FMEA) to identify required controls.

### **Conclusions**

This system poses no added risk to safety.