

# DENVU L.C.

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## 510(k) SUMMARY

Submitter's name: DenVu L.C.

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### Device name:

Proprietary name: DIMS (Digital Imaging and Medical System),  
Model CL1-5110 and Model CL1-5111.

Common or usual name: Picture archiving and communications system  
(PACS).

Classification name: Proposed classification: Picture archiving and  
communications systems (PACS), Class II,  
21 CFR 892.2050.

### Legally marketed device for substantial equivalence comparison:

Wallach Digital Imaging System submitted by Wallach Surgical Devices, Inc. and  
cleared for marketing under 510(k) \*K950630.

### Description of the device:

The DIMS (Digital Imaging and Medical System) is a picture archiving and  
communications system. Hardware components are purchased from other  
manufacturers. Two models will be provided, distinguished only by the size of their  
monitors. Software runs in the Windows 95 format.

### Intended use of device:

The DIMS (Digital Imaging and Medical System) is intended to be used as a  
picture archiving and communications system during colposcopy procedures.

### Technological characteristics:

The DIMS device can display, process, digitize, store, and transmit images  
obtained during colposcopy examinations using hardware and software  
components.

### Testing conducted:

Software testing was conducted as part of the development process.

### Performance testing:

Comparative performance testing and clinical evaluations were not submitted as  
part of this 510(k).