



Medical Device Regulation of PACS Devices

**Robert Phillips, PhD.
Chief, Radiological Devices Branch
Office of Device Evaluation
CDRH**

Outline

- **Device Classification**
- **Market Clearance Processes**
- **PACS Classification and Regulation**
- **Issues with Compression**
- **Digitizers**
- **FFDM Approvals**

Device Classification

- **Medical device amendments passed 1976**
- **Revised several times**
- **All devices on market prior to 1976 were grand fathered**
- **Grand fathered devices places into 3 classifications**

Device Classifications

- **Class 1 – General controls**
- **Class 2 – General controls and special controls**
- **Class 3 – PMA necessary**

510(k) Process

- **Primarily applies to Class 1 and 2**
- **New device is shown to be “substantially equivalent” to a device already on the market**
- **Essentially a “me too” process**
- **New device is no more safe or effective than the old device**

510(k) Process

- **Technology creep can occur**
- **No requirement for new device to be better than the old device**
- **Center clears about 4000 510(k)s per year**

PMA Process

- **New device is shown to be safe and effective**
- **Device is judged on only its own characteristics**
- **Center approves about 35-50 PMAs per year**

PACS Classification

- **PACS work station (includes CRTs and other softcopy devices)**
- **Communications devices**
- **Data storage devices**
- **Hardcopy output devices**
- **Digitizers**

Communications and Storage Devices

- **Class 1**
- **Exempt from 510(k) submission**
- **Technology is driven by computer industry**

Hardcopy, digitizer, and PACS workstation

- **Class 2**
- **510(k) submission necessary**
- **Device marketed with general claim**
- **Device operation critical to diagnostic process**

Non-lossy Compression

- **Restored data is essentially identical to original**

Issues with data compression

- **Used to make data transmission and storage more efficient**
- **Can be either “lossy” or “non-lossy”**
- **Most common standard is JPEG
2000(Joint Photographic Experts Group)**
- **Old rule of thumb (JPEG) – compression greater than 4:1 was lossy**

Issues with data compression

- **All derivative images after lossy compression must carry a warning label**
- **Newer technologies (Wavelets) allow higher non-lossy ratios (JPEG 2000)**
- **We have not cleared lossy compression for mammography use**
- **Use may be hidden**

Prior to Compression



JPEG 40:1



JPEG2000 40:1



Compression References

Wavelet tutorial

www.amara.com/IEEEwave/IEEEwavelet.html#contents

JPEG tutorial

www.ece.purdue.edu/~ace/jpeg-tut/jpegtut1.html

www.stanford.edu/~udara/SOCO/lossy/jpeg/index.htm

JPEG2000 General Information

www.dspworx.com/primer_jpeg2000.htm

JPEG2000 Tutorial

www.lkn.ei.tum.de/studium/mmprog/jpeg2000/JPEG2000_Tutorial.htm

Digitizers

- **Used to convert a conventional image into a digital image**
- **Used to process or manipulate images**
- **Precursor to some CAD devices**
- **Cleared with general IFU**
- **Not cleared for mammography use**

Full Field Digital Mammography

- **Several different technologies are being used**
- **Was unable to establish substantial equivalence (inter and intra-reader variability too high)**
- **Three devices have been approved**
- **MQSA QC info based on individual testing provided by the sponsor, no general QC approach yet**