

**Summary of Safety and Effectiveness for
ALI comPACS Data Compression Module for Diagnostic Images**

8.1 Demographic Information

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8.1.1 Date Prepared

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8.1.2 Submitter

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8.2 Device Name

8.2.1 Trade or Proprietary Name

ALI comPACS Data Compression Module for Diagnostic Images

8.2.2 Common Name

ALI comPACS Data Compression Module for Diagnostic Images

8.2.3 Classification Name

There is no official FDA classification name for this accessory. The common name used by FDA for these devices is *Picture Archiving and Communications Systems*.

8.3 Devices to which Substantial Equivalence is being Claimed

CEMAX-ICON Archive Manager 2.0 and Autorad modules (K955092).

8.4 Device Description

8.4.1 Function

The ALI comPACS Data Compression Module for Diagnostic Images is an accessory to the ALI UltraPACS (K925965/A) Picture Archiving and Communication System.

ALI comPACS operates as follows:

1. The clinical operator selects the functions where lossy compression is to be applied (archiving, viewing, transmitting, still images, videos) .
2. The clinical operator selects the compression ratio based on medical preference of two images/videos, one the original image/video and the second the image/video compressed to the desired lossy compression ratio.

3. The clinical operator proceeds with use of ALI UltraPACS. Images/videos that have been lossy compressed have the characters "LOSSY xx:1" (where xx is the compression ratio) placed in the visible, non-diagnostic area of the image or video.

8.4.2 Scientific Concept

ALI comPACS uses industry standard JPEG and Motion JPEG lossy compression for the compression of digitized diagnostic still images and digitized video of diagnostic images, respectively. The scientific concept of JPEG compression is defined in the ISO /IEC standard ISO/IEC 10918-1 Digital Compression and Coding of Continuous Tone Still Images. Motion JPEG is a file format for the storage of sequentially JPEG compressed frames of video.

8.4.3 Significant Physical and Performance Characteristics

For compression of digitized diagnostic still images

Compression Method	JPEG Lossy Compression
Compression Ratio Range	4:1 up to 10:1
Original Diagnostic Image Size (pixels and depth)	Greyscale 640 horizontal x 480 vertical (NTSC), 256 levels (8 bit) 768 horizontal x 576 vertical (PAL), 256 levels (8 bit) Colour 640 horizontal x 480 vertical (NTSC), 16.7 million colours (24 bit) 768 horizontal x 576 vertical (PAL), 16.7 million colours (24 bit)
DICOM 3.0 Compliant	Yes
Functions where Compression can be applied	Archiving, Viewing, Transmitting

For compression of digitized video of diagnostic images

Compression Method	Motion JPEG Lossy Compression
Compression Ratio Range	4:1 up to 30:1
Compatible Video Signals	Composite Video, S-Video, NTSC, PAL
Capture Rate	Up to 30 frames/second (NTSC), 25 frames/second (PAL). Up to 60 fields/second (NTSC), 50 fields/second (PAL).
Frame Dimensions (in pixels)	Up to 640 horizontal x 480 vertical (NTSC), Up to 768 horizontal x 576 vertical (PAL)
Colour Depth	YUV 4:2:2, 16.7 million colours (24 bit colour)
Maximum Length of Captured Video	120 seconds
Functions where Compression can be applied	Archiving, Viewing, Transmitting

8.5 Statement of Intended Use

The ALI comPACS Data Compression Module for Diagnostic Images is an accessory to the ALI UltraPACS (K925965/A) Picture Archiving and Communication System. Through the use of JPEG and Motion JPEG lossy compression, ALI comPACS is intended to provide:

1. significant reductions in the amount of electronic storage space for digitized diagnostic still images and digitized video of diagnostic images while maintaining medically acceptable diagnostic quality of the images; and

2. significant reductions in the amount of time to transmit digitized diagnostic still images and digitized video of diagnostic images from storage to viewing sites, while maintaining medically acceptable diagnostic quality of the images.

8.6 Comparison of Technological Characteristics

The ALI comPACS Data Compression Module for Diagnostic Images is substantially equivalent to the CEMAX-ICON Archive Manager 2.0 and Autorad modules (K955092). Archive Manager 2.0 and Autorad, with its related Telemax software module (for viewing images under Windows 95 or MAC) and Imagecom software modules (for image transmission) use JPEG compression for viewing, transmitting, and archiving images using lossy compression.

Feature	ALI comPACS	CEMAX-ICON product
Uses JPEG lossy compression in viewing images	Yes	Yes (Autorad, Telemax)
Uses JPEG lossy compression in transmitting images	Yes	Yes (Imagecom)
Uses JPEG lossy compression for archiving images	Yes	Yes (Archive Manager 2.0)
Uses Motion JPEG for viewing digital video of medical images	Yes	No (limited to still frame images)
Uses Motion JPEG for transmitting digital video of medical images	Yes	No (limited to still frame images)
Uses Motion JPEG for archiving digital video of medical images	Yes	No (limited to still frame images)
Compression level bounded	Yes	Yes (fixed value)
DICOM 3.0 compliant for still images (DICOM does not yet address digital video)	Yes	Yes

The major difference between ALI comPACS and the CEMAX-ICON products Archive Manager 2.0 and Autorad is that ALI comPACS provides viewing, transmission, and archiving of lossy compressed digital video. ALI comPACS uses Motion JPEG for compressing the digital video of the diagnostic images. Motion JPEG is an intraframe JPEG compression format (i.e. JPEG applied to each frame, then each frame is stored), which is essentially a storage format for sequential JPEG compressed images presented at a chosen frame rate. Thus Motion JPEG compression does not raise any additional issues of safety or effectiveness beyond those already addressed by JPEG compression itself.

In conclusion, ALI comPACS is substantially equivalent to the CEMAX-ICON products Archive Manager 2.0 and Autorad.