

K961160

A.

1. Submittals:

Base Ten Systems, Inc.
One Electronics Drive
Trenton, New Jersey 08619-0151
Voice: (609) 586-7010
Fax: (609) 586-1593
Contact Person: Richard J. Farrelly
Date of Preparation: 13 May 1996

JUN 11 1996

2. Name of Device:

Trade or Proprietary Name: uPACS™ Version 1.7

Company or Usual Name: Picture Archiving System
(Established Name)

Classification Name: Device, Digital Image Storage - 90LMB
Digitizers, Image - 90LMA

3. Predicate Devices:

Intrascan

and

Intrascan II

Manufactured by:

Mark Solutions, Inc.
Mark Care Medical Systems, Inc.
87 Route 17 North
Maywood, New Jersey 07607
Telephone: (201) 368-8118

4. Device Description:

uPACS Version 1.7 is a software controlled microprocessor based archiving system using installed proprietary software for capturing, storage, archiving and presentation of video ultrasound images. The system is designed for connection to and use with FDA cleared ultrasound imaging equipment which provides video output and is cleared for operation and use in the patient environment. uPACS Version 1.7 can also accept images stored on magneto-optical (MO) disks, captured remotely, in video output form.

In the standard uPACS Version 1.7 configuration, an FDA cleared ultrasound imaging device (scanner) is connected to an IBM-compatible personal computer (PC) or to a remote capture unit (not part of the uPACS Version 1.7 system) which stores but does not archive images on an MO disk. Images captured by the scanner, or captured remotely and imported to uPACS Version 1.7 on an MO disk, are displayed on the monitor of the PC along with any text that is typed on the PC keyboard. The ultrasound image and patient text data can be stored on a CD-ROM in the PC, and images can be exported to a medical quality printer by the PC.

uPACS Version 1.7 enables users to perform the following system functions:

- ❖ View live images from user provided FDA approved ultrasound scanners or other NTSC or PAL video sources;
- ❖ Capture single-frame images from ultrasound scanners or other NTSC or PAL video sources;
- ❖ Import images, captured remotely, on an MO disk;
- ❖ Obtain text data directly from captured images;
- ❖ Edit text and image data before permanent storage;
- ❖ Review stored images on the system and on CD-ROM;
- ❖ Display up to four images at a time for review;
- ❖ Place notations directly on images;
- ❖ Archive images using CD-ROM;
- ❖ Export images to diskette, MO disk, and user provided printer(s);
- ❖ Provide a means for user training and proficiency demonstration;
- ❖ Assign security privileges to specific users in accordance with clinical access criteria.

5. *Intended Use Statement:*

uPACST[™] Version 1.7 is a software controlled microprocessor based archiving system using installed proprietary software for recording, storage and presentation of video ultrasound images. The system is designed for use with FDA approved ultrasound imaging equipment which provides video output and is approved for operation and use in the patient environment.

- 6.** The technological characteristics of the uPACST[™] Version 1.7 Device are essentially the same as that of the predicate device.
- B.** The determination of substantial equivalence is not based on an assessment of performance data.