

K961680

510(k) Summary  
For  
Sony DKR-700 Digital Still Recorder

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1. Applicant

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2. Device Name

Proprietary Name: Sony DKR-700 Digital Still Recorder

Common/Usual Name: Digital Still Image Recorder

Classification Name: Accessory to Medical Imaging Devices

Classification Status:

Video recorders have not been classified separately under Section 513 of the Act, but are considered to be accessories to medical imaging devices. The Sony DKR-700 Digital Still Recorder is an accessory to devices such as fluoroscopic X-ray systems (21 CFR 892.1660, Product Code 90JAB) and angiographic X-ray systems (21 CFR 892.1600, Product Code 90IZI) which have been classified as Class II devices and were reviewed by the Radiological Devices Panel.

### **3. Predicate Devices**

- Sony DVR-10 Digital Videocassette Recorder  
Sony Medical Systems Division  
K913886
- Sony Laser VideoDisc Recording (LVR) System  
Sony LVR-5000A/LVS-5000A Laser VideoDisc Recorder/Processor  
Sony Medical Systems Division  
K921275

### **4. Device Description**

The Sony DKR-700 Digital Still Recorder is a general purpose electronic device for digitally recording both color and black and white still images from a variety of analog sources in either a noncompressed or compressed mode to a Sony Magneto Optical (MO) MiniDisc. Recorded images may then be played back from the MO disc and viewed on a standard (analog) video monitor, or may be transmitted via a SCSI interface for importing into a PC/Windows application environment. With the DKR-700, information such as date, image number and image name can be attached to each image. Specific images can then be searched for and retrieved at the user's request.

The major components of the Sony DKR-700 Digital Still Recorder are the recorder, the recording media and the DKR-700 plug-in software. The RM-C700 Remote Control Unit and foot switches are optional accessories for external control of the device.

### **5. Intended Use**

The Sony DKR-700 Digital Still Recorder is intended for use in the recording of video images obtained from medical imaging systems for purposes such as administration, patient record archival storage and education. For example, the DKR-700 Digital Still Recorder can be utilized for recording images acquired by video cameras, fluoroscopic X-ray systems, angiographic X-ray systems, optical microscopes or other systems which produce a compatible video signal.

## 6. Technological Characteristics

The Sony DKR-700 Digital Still Recorder is intended as an addition to the Sony video recorder product line and has the same purpose and function as the predicate devices identified above. All of these Sony recorders have the same intended use, to record video images generated by medical imaging systems primarily for purposes of patient record archival storage and education.

All of the devices accept standard video signals produced by a wide range of equipment. The primary difference between the Sony DKR-700 and the predicate devices is the recording media used. The Sony DKR-700 uses a magneto-optical disc; the Sony DVR-10, a SMPTE format videocassette; and the Sony LVR System, an optical disc. All of these recording media are widely used in video recording systems for medical applications.