



August 12, 2002

VIA CERTIFIED MAIL

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Rm. 1-23
12420 Parklawn Dr.
Rockville, Maryland 20857

RECEIVED

AUG 16 2002

CDR/CDER

RECEIVED
AUG 16 2002
CDR/CDER

REQUEST FOR ADVISORY OPINION

Pursuant to 21 C.F.R § 10.85 (2001), the undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to device classification and resulting manufacturer responsibility for data and image archiving technology.

A. Issues involved

- 1) Whether the manufacturer of an information archive may market and/or sell the archive directly to a medical facility/end-user for use in archiving information and digital images.
- 2) Whether the archive falls under the purview of the FDA as a Medical Device, and, if so, at which classification level.
- 3) Whether the manufacturer of an information archive falls under the purview of the Good Manufacturing Practices, 510(k) filing requirements, and related Medical Device regulations, based on the nature of the data contained in the archive, where the archive serves a back up, disaster recovery, and business continuity function.
- 4) Whether the device status, as defined by FDA Classification, is altered when an archive, originally purchased by a medical facility for use as a hospital information system (HIS) archive is subsequently used by the medical facility to store digital images along with HIS data.
- 5) Whether the medical facility/consumer is deemed to have "altered" a medical device, and, thus, required to comply with additional FDA regulations when adding digital images to an archive previously containing hospital information only.

02A-0379

AP1

- 6) Whether the medical facility/consumer is deemed to have “altered” a medical device, and thus, required to comply with additional FDA regulations when adding hospital information system data to an archive previously containing digital images only, and is the outcome of this inquiry different if the digital image archive is part of a PACS, prior to integrating hospital information system data.
- 7) Whether the medical facility/consumer is deemed to have “altered” a medical device, and thus, required to comply with additional FDA regulations when integrating an existing archive, which contains hospital information system data, into a PACS to perform the image archiving function of the PACS.

B. Statement of fact and law

Confusion continues to exist in the healthcare industry as to the application of FDA Guidance and the related regulations with respect to Picture Archiving and Communication Systems and Archiving technologies (PACS), and their manufacturers.

- According to FDA Industry Guidance materials, manufacturers of general purpose image management products, including storage devices, not labeled or promoted for medical use¹ are exempt from registration, listing and pre-market notification. Upon integration into a medical image management system, however, by another manufacturer, a general-purpose image management product becomes a medical device, requiring the medical image management system manufacturer to comply with regulations regarding the medical use of this device.²

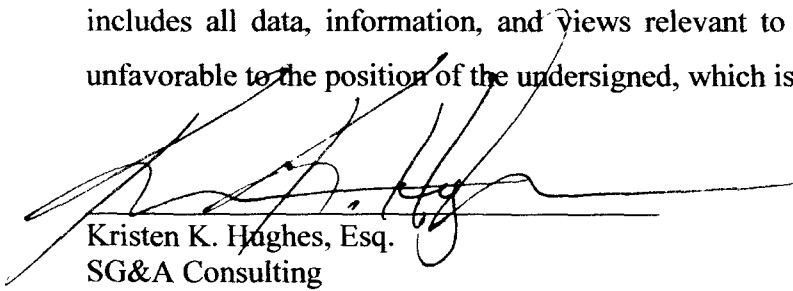
¹ 21 C.F.R. §§ 807.65(c).

² *Guidance for the Submission of Pre-Market Notifications for Medical Image Management Devices*, U.S. Dept. Health and Human Services, FDA, Center for Devices and Radiological Health, Radiological Devices Branch, Division of Reproductive, Abdominal, and Radiological Devices, Office of Device Evaluation, July 27, 2000, available at <http://www.fda.gov/cdrh/ode/guidance/416.html>.

- Pursuant to 21 C.F.R. § 892.2050 Picture Archiving and Communications Systems (PACS) may include “digital data storage devices” as parts of the “system.” amongst other features. PACS are currently classified as Class II devices.³ According to further guidance promulgated by the FDA in the Guidance materials, the *entire* PACS is deemed a Class II, and the individual parts, when *not* marketed or sold by the respective, individual manufactures, are evaluated individually, and not necessarily deemed Class II devices until incorporated into the PACS.
- The Guidance documentation further explains that data storage devices/archiving technologies, are *not* considered Class II devices,⁴ although PACSs, a compilation of various technological components *are* considered Class II devices, subject to filing requirements of all Class II devices.

The issues enumerated in Para. A, above, therefore, rest on the Department’s interpretation of “labeled or promoted for medical use,” and whether the library function and/or disaster recovery functions of an image and/or information archive is deemed “medical use.”

The undersigned certifies that, to the best of her knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.



Kristen K. Hughes, Esq.
SG&A Consulting
1701 E. Lamar Blvd., Ste. 160
Arlington, TX 76006
817.277.2558

³ 21 C.F.R. §§ 892.2050 (b).

⁴ See *supra*, note 2.