DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kristen K. Hughes, Esq.
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JUL - 3 2003

Re: C030030
Trade/Device Name: PACS Software
Dated: March 27, 2003
Received: March 28, 2003

Dear Ms. Hughes:

This is in response to your letter of August 12, 2002 requesting an advisory opinion with respect to device classification and resulting manufacturer responsibility for data and image archiving technology. As you know, this was converted to a 513(g) request on March 24, 2003. We apologize for the delay in responding to your request.

You are correct that a general purpose image management product, including a storage device not labeled or promoted for medical use, becomes a component of a medical device upon integration into a medical image management system by another manufacturer. However, compliance with regulations regarding the medical use of this device is the responsibility of the medical device manufacturer, not the manufacturer of the general purpose image management product. The manufacturer of the general purpose image management product is exempt from the regulations regarding medical use.

You are correct that Picture Archiving and Communications Systems (PACS) may include "digital data storage devices" as parts of the system. PACS are currently classified as Class II devices. The entire PACS is deemed Class II (Special Controls), although the individual parts may not be Class II until incorporated into a PACS.

The "Identification" of a PACS provided in 21 CFR 892.2050 states "A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images". The classifications for Medical Image Communications Devices (21 CFR 892.2020, Class I) and Medical Image Storage Devices (21 CFR 892.2010, Class I) are intended to include only medical image management devices whose principal functions are communications or storage. Classification 892.2050 is intended to include devices that have additional functions.

If the principal functions of a device is storage or communications it is considered Class I. If it provides digital processing functions, it may be Class II, depending on the complexity of the digital processing functions. Simple manipulations that do not alter the image data, such as window and level, pan and zoom, and image annotation are considered within the scope of the of communications and storage functions. However, image processing functions which are intended to alter the image data (e.g. filtering, multiplanar reconstruction, and 3D reconstruction) are considered to be outside the scope of storage and communications functions. Also, complex quantitative functions (e.g. arterial stenosis evaluation, ventricular volume calculations and calcium scoring) are not considered to be communications and storage functions. Devices which incorporate such functions are treated as PACS, which are Class II devices requiring premarket notification.

In response to the issues listed in Section A of your letter, specific responses are as follows:

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.

Response

Yes, 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. This may be a general purpose information archive, or a device marketed for medical use. If the device is marketed for medical use the manufacturer is subject to the regulations as a medical device.

2) Whether the archive falls under the purview of the FDA as a Medical Device, and, if so, at which classification level.

Response

If marketed for medical use, the device is subject to regulation by FDA as a medical device. Archiving devices are considered to be Medical Image Storage Devices under 21 CFR 892.2010, class I, exempt from premarket notification.

3) Whether the manufacturer of an information archive falls under the purview of the Good Manufacturing Practices, 510(k) 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.

Response

The nature of the data contained in an information archive has no bearing on whether the manufacturer falls under the purview of the Good Manufacturing Practices, 510(k) requirements or related medical device regulations. The medical device regulations apply if the device is intended for medical use.

4) Whether the device status, as defined by the 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.

Response

The device status, as defined by the FDA Classification, is not altered when an archive, originally purchased for use as an HIS archive, is subsequently used by the medical facility to store digital images. This is considered to be "practice of medicine". The FDA classification is determined by the intended use of the device when marketed.

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.

Response

A medical facility/consumer is not required to comply with FDA regulations as a result of altering a medical device unless they market the altered device in interstate commerce.

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.

Response

See response to question 5.

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.

Response

See response to question5.

Please contact Loren A. Zaremba, Ph.D. at (301) 594-1212 ext. 137 or by email at lzz@cdrh.fda.gov if you have any further questions.

Sincerely yours,

Daniel G. Schultz, M.D.
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Office of Device Evaluation
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