M. Premarket Notification [510(k)] Summary K973805

JAN - 2 1998

This summary document is being submitted in accordance with section 807.92(c).

The submitter of the 510(k) is:

George M. Treiber, Vice President, Chief Technical Officer
StorCOMM, Inc.
8849 San Jose Boulevard
Jacksonville, FL 32217
904-731-1289 Voice
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Date Summary Prepared: June 25, 1997

Device Subject to this 510(k):

Trade Name: ImageACCESS® System

Common Name: Clinical Image Management System

Classification Name: Medical Image Digitizer,
Proposed 21CFR 892.2050, Class II;
FR Vol.61, No 232, 12/2/96

Comparison with Predicate Devices:

The device which is the subject of this 510(k), ImageACCESS®, is substantially equivalent to the same device before the current modifications which was authorized for marketing via 510(k) K931454, decision date 12/14/93.

Device Description:

The ImageACCESS® system is a complete clinical image management system providing direct capture, retrieval, storage, and transmission of images, reports and patient demographics. These images include, but are not limited to, Flat film Radiology, computer Tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET). Images from such devices are directly recorded/retrieved on/from optical disk recorders.

Indications for Use:

The intended use of the device is to allow storage and retrieval of medical images for purposes of assisting in the diagnosis and/or treatment of diseases.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

George M. Treiber
Vice President, Chief Technical Officer
StorCOMM, Inc.
8649 Baypine Road
#7 Corporate Plaza
Jacksonville, FL 32256

Re: K973805
ImageACCESS®, Clinical Image Management System
Dated: September 25, 1997
Received: October 6, 1997
Unclassified
Procode: 90 LMD

JAN - 2 1998

Dear Mr. Treiber:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K973805

Device Name: IMAGE ACCESS©

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973805

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)