



STATEMENT

This document is a statement describing the use of two different DICOM viewing applications: iQ-VIEW and K-PACS.

iQ-VIEW

European Union

According to COUNCIL DIRECTIVE 93/42/EEC any medical device or any software to be used in the European Union to store human X-RAY images is classified as a medical device class IIa. iQ-VIEW has been registered as a medical device class IIa in the European Union since 2005. The notified body is MEDCERT (Notified Body ID: CE 0482).

United States of America

According to the Code of Federal Regulations Title 21, Subchapter H, Part 892, Subpart B, Section 892.2050 (revised as of April 1, 2010), any device or software that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images is classified as a medical device class II.

iQ-VIEW, as part of iQ-SYSTEM PACS, has been registered as a medical device class II according to chapter 510(k) at the Food and Drug Administration in the United States (FDA) since 2006 under the registration number K062488.

iQ-VIEW may be therefore used as a medical device in the European Union, United States of America and many other countries to record, process, display and read medical imaging studies.

K-PACS

K-PACS has never been registered as a medical device neither in the European Union nor in the United States of America. K-PACS can be used for testing and evaluation purposes and for private use. K-PACS CANNOT be used as a device or software to record, process, display and read human or veterinary X-RAY images in the whole world according to the End User License Agreement. It CANNOT be used as a medical device in the European Union according to COUNCIL DIRECTIVE 93/42/EEC.

K-PACS CANNOT be used as a device or software to record, process, display and read human medical images in the United States of America according to the Federal Drug, Food & Cosmetic Act (FD&C) Part V, chapter 510(k).

For the correctness of the abovementioned information:

London, October 1, 2010

Christian Jorga
Quality Management Representative
IMAGE Information Systems Ltd.

Enclosures

EC Declaration of Conformity iQ-VIEW
Certificate EN ISO 13485:2003 IMAGE Information Systems Ltd.
FDA Certificate iQ-SYSTEM PACS

Office 404 | 4th floor

Albany House

324/326 Regent Street

London | W1B 3HH

United Kingdom

Tel.: + 44 207 193 06 20

Fax: + 44 207 976 48 97

info@image-systems.biz

Registered in England & Wales

Company Number: 5000 773

VAT ID: GB 849164496

UK Bank Account:

Account No.: 82035855

Branch Sort Code: 40-03-28 (HSBC)

IBAN: GB62MIDL40032882035855

BIC: MIDLGB2106U

German Bank Account:

Account No.: 7900

Bank Code: 230 641 07

(Raiffeisenbank Hagenow)

IBAN: DE8423064107000007900

BIC: GENODEF1BCH



EC Declaration of Conformity

The named manufacturer
IMAGE Information Systems Ltd.
Office 404, 4th floor
Albany House
324/326 Regent Street
London, W1B 3HH
United Kingdom
www.image-systems.biz

hereby attests that the medical device stated as follows:

iQ-VIEW

- classified as category IIa -

complies with all applicable directives below:

Council Directive 93/42/EEC

The compliance with the procedure stated above is permanently monitored by the named manufacturer who declares its sole responsibility and whose quality management system is periodically kept under surveillance by the "Notified Body".

MEDCERT GmbH
Pilatuspool 2
D-20355 Hamburg
Germany
Notified Body CE 0482

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Albany House
324/326 Regent Street
London | W1B 3HH
United Kingdom

Tel.: + 44 207 193 06 20
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info@image-systems.biz

Registered in England & Wales
Company Number: 5000 773
VAT ID: GB 849164496

London, March 19, 2010

Mike Jensen
MD

Arpad Bischof
MD/SO/SM

UK Bank Account:
Account No.: 82035855
Branch Sort Code: 40-03-28 (HSBC)
IBAN: GB62MIDL40032882035855
BIC: MIDLGB2106U

German Bank Account:
Account No.: 7900
Bank Code: 230 641 07
(Raiffeisenbank Hagenow)
IBAN: DE84230641070000007900
BIC: GENODEF1BCH



Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Vorsetzen 35 – 20459 Hamburg – Germany

herewith confirms that the company

IMAGE Information Systems Ltd.
Office 404, 4th Floor, Albany House, 324/326 Regent Street
London W1B 3HH – United Kingdom

and their facility
IMAGE Information Systems Europe Ltd.
Lange Straße 16 – 18055 Rostock – Germany

has introduced and applies a Quality Management System in the area of

**Design, manufacture, installation and service of
digital image processing systems**

A Quality Audit demonstrated compliance of the Quality Management System with

EN ISO 13485:2003 + AC:2007

The certification assumes that the company is applying and maintaining its
Quality Management System according to the above given standard. The license of
certification is subject to surveillance by MEDCERT.

This certificate is valid until: 15 February 2013
Hamburg, 05 May 2009

Process No.: QS - 3420
Certificate No.: 3420GB431090505

MEDCERT Certification Body
(Frank Wilmerstädt)



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.99.02-46

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

August 17, 2006

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Arpad Bischof MD
IMAGE Information Systems Ltd.
15 Perham Road
London, W14 9SR
United Kingdom
Phone: +44 207 904 18 51
Fax: +44 207 904 18 52

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name: iQ-System PACS
Common Name: Picture Archiving Communications System
Classification Name: system, image processing, radiological
Product code: LLZ

Predicate Device: 21 CFR 807.92(a)(3)

FDA has classified the predicate device (K052358) as Class II, CFR 892.2050, LLZ. It is our understanding that iQ-System PACS device falls under the same classification as the predicate device. Predicate device details are as follows:

Device Classification Name	system, image processing, radiological
510(k) Number	K052358
Regulation Number	892.2050
Device Name	ETIAM STAR PACS COMPONENTS
Applicant	ETIAM, S.A.
Classification Product Code	LLZ
Decision Date	10/05/2005

Device Description: 21 CFR 807.92(a)(4)

iQ-System PACS is a software device for network or web-based medical image viewing and manipulation, running on Windows 2000/XP. It is adapted for, storing, processing routing and report generating.

iQ-System PACS fully supports the DICOM standard and has functionality for advanced DICOM viewing, Hanging Protocol, and 3D image processing (Orthogonal and Oblique Multiplanar Reconstructions (MPR), Maximum Intensity Projections (MIP), Surface Shaded Display (SSD), and Volume Rendering (VRT)). The main iQ-SYSTEM PACS modules are iQ-LITE, iQ-Print, iQ-View (including iQ-3D), and iQ-Web.

Indications for Use: 21 CFR 807 92(a)(5)

iQ-System PACS is a software device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware.

Images and data can be captured, stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with clinical application.

Technological Characteristics: 21 CFR 807 92(a)(6)

iQ-System PACS is a software device that handles and manipulates digital medical images.

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification iQ-System PACS contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The submission contains the results of a hazard analysis and the "Level of Concern" for potential hazards has been classified as "Minor".



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 19 2006

IMAGE Information Systems Ltd.
% MR. Carl Alletto
Consultant
OTech, Inc.
1600 Manchester Way
CORINTH TX 76201

Re: K062488

Trade/Device Name: iQ-System PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 10, 2006
Received: August 29, 2006

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number: K062488

Device Name: iQ-System PACS

Indications for Use:

iQ-System PACS is a software device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware.

Images and data can be captured, stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations.

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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)

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Caroleen Y Newland for N.C. Brogden
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062488