NOV 17 2005

510(k) Summary
for the IDX Systems Corporation
Imagecast™ PACS

K052618

1. SUBMITTER/HOLDER

IDX Systems Corporation
40 IDX Drive P.O. Box 1070
Burlington, VT 05402

Contact Person: Dan McKibben
Telephone: 802-859-6003

Date Prepared: September 6, 2005

2. DEVICE NAME

Proprietary Name:	Imagecast™ PACS
Common/Usual Name:	PACS
Classification Name:	Picture archiving and communication system

3. PREDICATE DEVICE

iSite PACS System, K042292, Stentor, Inc.

4. DEVICE DESCRIPTION

The Imagecast™ PACS is a modification of the iSite PACS that replaces the iSite worklist software with the Imagecast™ Worklist software. The Imagecast™ PACS is designed to optimize the clinician's workflow, and targets activities fundamental to their work: organizing, finding, reading, sharing and reporting. The Imagecast™ PACS trade name is also currently in use by IDX to resell the iSite PACS product.

5. INTENDED USE

Imagecast™ PACS is an image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical

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technicians. The system is used with general purpose computing hardware to acquire, transmit, process and store images and data throughout a clinical environment. Data and images are acquired through DICOM compliant imaging devices and modalities.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA-approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by the FDA.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Imagecast™ PACS is substantially equivalent to the iSite PACS in intended use, indications for use, technological characteristics and operational characteristics.

7. PERFORMANCE TESTING

Prospectively defined verification and validation activities for the Imagecast™ PACS assure that the Imagecast™ PACS is substantially equivalent to the cleared iSite PACS and meets design and performance specifications as well as user needs when operated according to the operating instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2005

Mr. Dan McKibben
Executive Quality Management Representative
IDX IMAGECAST DIVISION
40 IDX Drive
PO Box 1070
BURLINGTON VT 05402

Re.: K052618
Trade/Device Name: Imagecast PCS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system.
Regulatory Class: II
Product Code: LLZ
Dated: November 8, 2005
Received: November 9, 2005

Dear Mr. McKibben:

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 (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 (PMA), it may be subject to 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.

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

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

510(k) Number (if known): K052618

Device Name: Imagecast™ PACS

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052618