K992352

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SEP 29 1999

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

510(k) Summary

1. Identification

Date Prepared:	July 11, 1999
Submitter	inTeleRadiology, Inc. 2400 Lorain Road San Marino, California 91108
Contact	Michael Vincent Klein, M.D. Phone: (626) 457-1789 Fax: (626) 457-1789

2. Device Name

Proprietary Name:	iTR2000™: internet Teleradiology™
Common Name:	Teleradiology Software
Classification Name:	System, Digital Image Communications

3. Registration Number:

Pending

4. Classification

Class:	2
Panel:	Radiology
Product Code:	LMD

510(k) Summary - *continued*

5. Standards

Performance: None established

Voluntary: American College of Radiology Standard for Teleradiology (Revision 35 - 1998; for small matrix systems)

ISO/IEC 10918-1 Digital Compression and Coding of Continuous-Tone Still Images [also known as Joint Photographic Experts Group (JPEG); Revision 13.July 1994]

6. Predicate Devices

WINRAD Teleradiology System (Line Imaging Systems)

AMICAS Web/Intranet Image Server (AutoCyt Group, Inc.)

7. Device Description

iTR2000™ is a stand-alone software product which may be marketed as a software-only product, as well as for use in conjunction with standard PC hardware, off-the-shelf software or third-party teleradiology/PACS software.

iTR2000™ provides short-term remote access to medical images by radiologists, referring physicians and other licensed professionals, utilizing a personal computer or workstation with internet access. Images are securely stored on a internet website for on-demand remote retrieval via the iTR2000™ software, or via a standard web browser without the use of propriety software. The iTR2000™ system employs the latest internet security techniques and meets all current federal medical communications standards including recent proposals from HCFA and HHS.

iTR2000™ is primarily intended to allow the transmission, retrieval and review of images produced by imaging equipment otherwise not part of a digital Picture Archive and Communication System (PACS) network or legacy equipment not compatible with ACR/NEMA DICOM 3.0. Conventional film-based images can be optically digitized and stored in a standard image format, such as JPEG. iTR2000™ can also be configured to web-enable third-party DICOM-capable teleradiology/PACS systems in low-volume environments for remote or on-call activities.

iTR2000™ is designed for use primarily with small-matrix matrix imaging modalities, such as images produced by Computed Tomography (CT), Ultrasound (US), Magnetic Resonance Imaging (MRI), Nuclear Medicine (NM), digital flourography and digital angiography. The use of images produced by large-matrix imaging systems, such as digitized radiographic films and computed radiography or mammography, requires the use of digitization and viewing equipment which exceed the stated minimum requirements for the standard iTR2000™ system. iTR2000™ does not control the actual image-taking system (i.e. x-ray, MRI, ultrasound or scintography machines).

8. Intended Use

iTR2000™ is a software communications tool intended to be used in the transportation, storage and retrieval of digital medical images for the purpose of off-site review.

9. Safety and Effectiveness

The iTR2000™ software is primarily an image communications software program used to transfer digital image files between personal computers and is utilized only by competent medical professionals. The system has no patient contacting components. The device does not impact the quality of the original acquired image data. It does not require specialized or nonstandard devices of any type. Competent health professionals would reasonably be expected to exercise judgment and professional expertise in the use and interpretation of the transferred image files.

Similar to the predicate devices, iTR2000™ can be used with image compression to remove redundant or unimportant information in the original image data. The recommended JPEG image compression libraries and default compression settings are believed to be substantially equivalent to the libraries used in the previously cleared products.

9. Testing

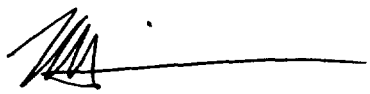
The safety of this program has been determined through the various stages of software development which included the development of product specifications, coding, testing, debugging, in-house validation and field maintenance. Functional testing including the transfer of diagnostic imaging studies for over 1200 complete studies. Standard data communications controls for error detection and correction are utilized.

10. Conclusions

iTR2000™ software is a medical device, and it has the same indications for use, the same technological characteristics and the same target population as the legally marketed predicate devices.

Any differences between the iTR2000™ software and the predicate devices have no significant influence on safety or efficacy. The iTR2000™ system employs the latest internet security techniques and meets all current federal medical communications standards including recent proposals from HCFA and HHS. No new issues of safety and effectiveness are raised.

InTeleRadiology, Inc., believes sufficient information is included to reach a determination of substantial equivalence. We conclude that the iTR2000™ software is as safe and effective as the legally marketed devices and is substantially equivalent to the previously marketed devices (as listed above in Part 6).



Michael Vincent Klein, M.D.

July 11, 1999

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1999

Michael Vincent Klein, M.D.
CEO
Inteleradiology, Inc.
2400 Lorain Road
San Marino, CA 91108

Re: K992352
ITR2000 Internet Teleradiology
Dated: July 11, 1999
Received: July 14, 1999
Product Code: 90 LMD
Regulatory Class: I (one)
21 CFR 892.2020

Dear Dr. Klein:

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K992352

Device Name: iTR2000

Indications For Use:

iTR2000 is a software communications tool intended to be used in the transportation, storage and retrieval of digital medical images for the purpose of off-site review.

(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 K992352

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)