

K984405

FEB 8 1999

IntraCom Corporation EchoLive™ PACS
Pre-Market Notification

510(K) SUMMARY STATEMENT

Applicant: IntraCom Corporation
1309 S. Mary Avenue
Sunnyvale, CA 94087

Contact James A. Nations
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E-mail: nations@qpt.com

Manufacturing Facility: IntraCom Corporation
1309 S. Mary Avenue
Sunnyvale, CA 94087

Establishment
Registration Number: Applied for, not yet received

Device Name: EchoLive™ Family
Models: ZL-1010
ZL-2000
ZL-2100
ZL-3000
ZL-4000

Common Name: Medical Image Management Device
Picture Archiving and Communication Systems (PACS)
Device Class: II

Panel: Radiology
LMD
21 CFR 892.2050

Performance Standards: 21 CFR 820 et.seq.
IEC Medical Device Directive EN60001
UL 544
The Society of Motion Picture and Television Engineers (SMPTE)
The National Electrical Manufacturers Association (NEMA)
American College of Radiology (ARC)
Digital Imaging and Communications in Medicine (DICOM)
IISO/IEC 10918-1 Digital Compression and Coding of Continuous-Tone Still Images
Joint Photographic Experts Group (JPEG)

Reason for submission: New PACS with substantial equivalence.

Product Description: The EchoLive™ medical image management device family is a PACS capable of digital real-time simulcast transmission of

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medical images. Each model varies in the particular features and capabilities it offers the medical professional.

Predicate Devices:	IntraCom Corporation	Class I Device, 21CFR892.2020
	Eastman Kodak	(k981053)
	StorCOMM, Inc.	(k973805)
	Sterling Diagnostic Imaging	(k980220) (k980970) (k973206)
		(k964250)
	A.L.I. Technologies, Inc.	Unknown
	Algotec Systems Ltd.	(k971347) (k980648)
	Access Radiology Corporation	(k972925) (k954691)
Olicon Imaging Systems, Inc.	(k973959)	
Autocytgroup, Inc.	(k970064)	

Indications For Use:

The EchoLive™ medical image management device family is designed for use in all medical specialties including, but not limited to, radiology, cardiology, gynecology, ENT, neurology, pediatrics, podiatry, chiropractic, general surgery, oral surgery and dentistry. The device may be used in medical offices and health care facilities, to facilitate access to clinical images and information, both archived and dynamic, in distributed locations over intranets, LANs, Internet, direct or dial dial-up telephone lines. The system may transmit a wide range of data including, but not limited to, Sonographs (Ultrasound images), Computer Tomography (CT), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET). In addition the device may communicate standard audio, video and digital transmissions and recordings, providing complete clinical imaging handling, providing direct capture, retrieval, storage, and direct transmission and printing of images, reports, and patient information.



FEB 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850James A. Nations, Esq.
Director, Regulatory Affairs
IntraCom Corporation
1309 S. Mary Avenue
Sunnyvale, CA 94087Re: K984405
EchoLive Family Models ZL-1010, 2000, 2100,
3000, 4000
Dated: November 25, 1998
Received: December 9, 1998
Regulatory class: I
21 CFR 892.2010/Procode: 90 LMB
21 CFR 892.2020/Procode: 90 LMD

Dear Mr. Nations:

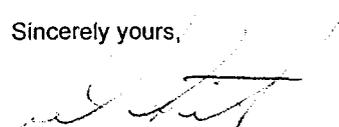
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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

510(k) number (if known): K984405

Device Name:

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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON OTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescriptions Use
(per 21 CFR 801.109)

[Handwritten Signature]
OR

Over-The-Counter Use *[Handwritten Signature]*

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984405

(OPTIONAL Format 1-2-96)