K041947

AUG 16 2004

Section 3: 510K Summary

Submitting Company Name:	**Innovative Imaging, Inc.** 9940 Business Park Drive* Suite 155 Sacramento, CA 95827 **Manufacturing and packaging also.*
Contact:	Cynthia Kendall, President & CEO **Tel** (800) 765-7226 **Fax** (916) 363-3815
Application Date:	July 1st, 2004
Name of Predicate Device:	I^3 SYSTEM-ABD™ Diagnostic Ultrasound
Model of Predicate Device:	Version 1 (V1)
Name of Modified Device: (For which this Special 510(k) is being submitted)	I^3 SYSTEM-ABD™ Diagnostic Ultrasound
Model of Modified Device: (For which this Special 510(k) is being submitted)	Version 2 (V2)
Establishment Registration No.:	2950189
Classification of Device:	Class II Ultrasound, Diagnostic
Original 510(k) Submission No.:	K902007

Reason for 510(k):
System software is being ported/rewritten utilizing a new Windows operating system. Existing I^3SYSTEM-ABD™ Diagnostic Ultrasound system hardware will remain the same.

Indications for Use:

- Cataracts
- Retinal Detachments (a separation of the retina from the middle coat of the eyeball)
- Orbital Lesions
- Tumors
- Foreign bodies
- Inflammation
- Vascular Irregularities

Intended Use:

The I^3SYSTEM-ABD™ is a diagnostic ophthalmic ultrasound instrument designed to be used by ophthalmologists for diagnosis of the eye. It is expected that the user is trained in operation of the instrument, and on the medical interpretation of ultrasonic images. The intended use is the same for the entire I^3SYSTEM-ABD™ product family.

Description and Comparison of Device:

The difference between the Version 2 system and the existing I^3 SYSTEM-ABD™ Diagnostic Ultrasound system is the operating system on which it runs. The new version has a 32-bit operating system, the current version has a DOS based operating system. No changes have been made to any external accessories or probes.

Verification and Validation:

All verification and validation tests have been performed as specified in the Design Controls Procedures (QAP 4.4) in conformance with 21 CFR 820.30. The tests have demonstrated that the unit complies with the intended functional requirements and system specifications.

Sterilization Information:

The I^3 SYSTEM-ABD Diagnostic Ultrasound unit is not a sterile device.

Proposed Labeling and Marketing:

There will be no changes to either the labeling or marketing of the I^3 SYSTEM-ABD Diagnostic Ultrasound.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2004

Ms. Cynthia Kendall
President & CEO
Innovative Imaging, Inc.
9940 Business Park Drive
Suite 155
SACRAMENTO CA 95827

Re: K041947
Trade Name: I^3 SYSTEM-ABD™ Diagnostic Ultrasound
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: July 1, 2004
Received: July 20, 2004

Dear Ms. Kendall:

We have reviewed your Section 510(k) premarket 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.

This determination of substantial equivalence applies to the following transducers intended for use with the I^3 SYSTEM-ABD™ Diagnostic Ultrasound, as described in your premarket notification:

Transducer Model Number

10 MHz Biometry A-Probe
8 MHz Diagnostic A-Probe
10MHz Diagnostic B-Scan
20MHz Diagnostic B-Scan

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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.
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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

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

This letter will allow you to begin marketing your device as described in your 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

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

Enclosures

I³SYSTEM-ABD Diagnostic System

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity imaging	Combined (specify)	Other (specify)
Ophthalmic	✓	✓								
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041947

10 MHz Biometry A-probe

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Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
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Transvaginal										
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Laparoscopic										
Musculo-skeletal Conventional										
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8MHz Diagnostic A-probe

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Fill out one form for each ultrasound system and each transducer.

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	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	✓									
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
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Laparoscopic										
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Division of **Reproductive, Abdominal,** and Radiological **Devices**

K041947

10 MHz Diagnostic B-scan

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	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic		✓								
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
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Musculo-skeletal Conventional										
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510(k) Number K041947

20 MHz Diagnostic B-Scan

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic		✓								
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
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