



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tom Davis
General Manager
Ellex Innovative Imaging
9940 Business Park Drive, Suite 165
SACRAMENTO CA 95827

JAN - 9 2009

Re: K083061
Trade/Device Name: I³ SYSTEM-ABD Ver.4.0 (Eye Cubed V4)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: December 4, 2008
Received: December 8, 2008

Dear Mr. Davis:

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 I³ SYSTEM-ABD Ver.4.0 (Eye Cubed V4), as described in your premarket notification:

Transducer Model Number

10MHz Posterior Segment B-scan

10MHz Biometric A-scan

8MHz Diagnostic A-scan

20MHz Anterior 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.

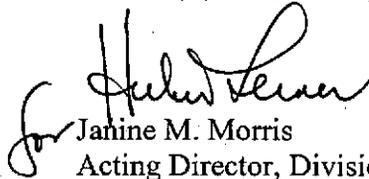
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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>

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (240) 276-3666.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)



3.1.1. Attachment: Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system

Transducer Name	Ophthalmic 10MHz Posterior Segment B-scan Transducer
Intended Use	Posterior 10MHz B-scan Imaging of the Eye
510(K) Number	K083061

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	Colour Doppler	Amplitude Doppler	Colour Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic		P								
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)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K083061

System-ABD Special 510(K)

3.1.2. Attachment: Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system

Transducer Name	Ophthalmic 10MHz Biometric A- scan Transducer
Intended Use	10MHz Biometric A-scan Imaging of the Eye
510(k) Number	K083061

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	Colour Doppler	Amplitude Doppler	Colour Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	P									
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: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number K083061



3.1.3. Attachment: Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system

Transducer Name	Ophthalmic 8MHz Diagnostic A- scan Transducer
Intended Use	8MHz Diagnostic A-scan Imaging of the Eye
510(K) Number	K083061

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	Colour Doppler	Amplitude Doppler	Colour Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	P									
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

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Prescription Use (Per 21 CFR 801.109)


(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083061

System-ABD Special 510(K)

3.1.4. Attachment: Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system.

Transducer Name	Ophthalmic 20MHz Anterior Segment B-scan Transducer
Intended Use	Anterior 20MHz B-scan Imaging of the Eye
510(k) Number	K083061

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	Colour Doppler	Amplitude Doppler	Colour Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic		P								
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)										

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