



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Jonathan Strawn
Business Manager
Ellex Innovative Imaging
9940 Business Park Drive, Suite 165
SACRAMENTO CA 95827

DEC 27 2010

Re: K103608
Trade/Device Name: Eye Cubed Version 4 Diagnostic Ultrasound
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: December 7, 2010
Received: December 9, 2010

Dear Mr. Strawn:

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 Eye Cubed Version 4 Diagnostic Ultrasound, as described in your premarket notification:

Transducer Model Number

40 MHz Anterior Segment B-Scan

10 MHz Posterior Segment B-Scan

10 MHz Biometric A-Scan

8 MHz Diagnostic A-Scan

20 MHz Anterior Segment 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 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

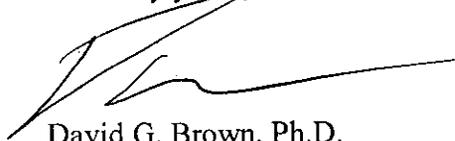
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Andrew Kang at (301) 796-6544.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): k103508

Device Name: Eye Cubed Version 4 Diagnostic Ultrasound

DEC 27 2010

Indications for Use:

The Eye Cubed V4 is indicated for use in ophthalmic imaging when the following conditions are present or suspected:

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

Refer to the Attachments for the Diagnostic Ultrasound Indications for Use Forms

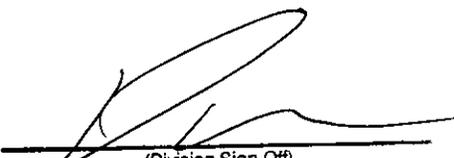
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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510K k103508



Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system

Transducer Name	Ophthalmic 40 MHz Anterior Segment B-scan transducer
Intended Use	Anterior 40 MHz B-scan imaging of the eye
510(k) Number	K103508

DEC 27 2010

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		N								
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:

Indicated use for - B-scan anterior segment imaging

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Concurrent use of CDRL, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K103608

13 System-ABD Special 510(k)



Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system

Transducer Name	Ophthalmic 10 MHz Posterior Segment B-scan transducer
Intended Use	Posterior 10 MHz B-scan imaging of the eye
510(k) Number	K083061, K103508

DEC 27 2010

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)										

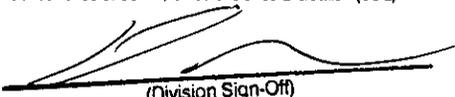
N= new indication; P=previously cleared by FDA; E=added under Appendix E.

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 Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K103608

I³ System-ABD Special 510(k)



Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system

Transducer Name	Ophthalmic 10 MHz Biometric A-scan transducer
Intended Use	10 MHz Biometric A-scan imaging of the eye
510(k) Number	K083061, K103508

DEC 27 2010

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:

Indicated use for - Biometric A-scan

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Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

13 System-ABD Special 510(k)

510K

K103508



Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system

Transducer Name	Ophthalmic 8 MHz Diagnostic A-scan transducer
Intended Use	8 MHz Diagnostic A-scan imaging of the eye
510(k) Number	K083061 , K103508

DEC 27 2010

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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Additional Comments:

Indicated use for - Diagnostic A-scan

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Prescription Use (Per 21 CFR 801.109)

Concurrence of CDPR, Office of Device Evaluation (ODE)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K103608

I³ System-ABD Special 510(k)



Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system

Transducer Name	Ophthalmic 20 MHz Anterior Segment B-scan transducer
Intended Use	Anterior 20 MHz B-scan imaging of the eye
510(k) Number	K083061 , K103508

DEC 27 2010

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

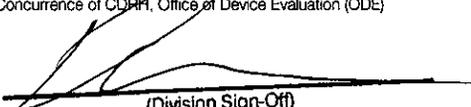
Additional Comments:

Indicated use for – B-scan anterior segment imaging

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Concurrence of CDRE, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


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 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K **K103608** 1st System-ABD Special 510(k)