DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Skip Rimer
Director, Quality Assurance & Regulatory Affairs
Life-Tech, Inc.
13235 N. Promenade Blvd.
STAFFORD TX 77477

APR 19 2012

Re: K120234
Trade/Device Name: eZono 3000
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed Doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: January 20, 2012
Received: January 25, 2012

Dear Mr. Rimer:

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 eZono 3000, as described in your premarket notification:

Transducer Model Number	
8LA	30CL60
8LA-SC	35CL20
12LA	35CL60

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" (21CFR 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 Jay Vaishnav at (301) 796-9584.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: eZono 3000

Indications for Use:

The intended use of the eZono 3000, as defined by FDA guidance documents, are:

Ophthalmic	Musculo-skeletal (Conventional)
Fetal (as enumerated in the IFU Tables)	Musculo-skeletal (Superficial)
Abdominal	Retroperitoneum
Pediatric	Female reproductive system and foetus
Small Organ (breast, thyroid, testicle)	Cardiac (Adult)
Invasive diagnostic or therapeutic procedures	Cardiac (Pediatric)
Peripheral vessel	

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

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

510(k) Number K120234

System: eZono 3000

Transducer: 8LA

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B + CD)	Other* (Color Power Doppler)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	N			P	P	N
	Small Organ (e.g. testicles, lymph nodes, thyroid)	P	N			P	P	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**	P	N			P	P	N
	Musculo-skeletal **(Superficial)**	P	N			P	P	N
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)	P	N			P	P	N
	Superficial structures & pathologies (incl. Lungs)	P	N			P	P	N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	N			P	P	N
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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

510K K120234

System: eZono 3000

Transducer: 8LA-SC

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B + CD)	Other* (Color Power Doppler)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	N			P	P	N
	Small Organ (e.g. testicles, lymph nodes, thyroid)	P	N			P	P	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**	P	N			P	P	N
	Musculo-skeletal **(Superficial)**	P	N			P	P	N
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)	P	N			P	P	N
	Superficial structures & pathologies (incl. Lungs)	P	N			P	P	N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	N			P	P	N
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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

510K K120234

System: eZono 3000

Transducer: 12LA

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B + CD)	Other* (Color Power Doppler)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric (excluding transcranial)	P	N			P	P	N
	Small Organ (e.g. testicles, lymph nodes, thyroid)	P	N			P	P	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**	P	N			P	P	N
	Musculo-skeletal **(Superficial)**	P	N			P	P	N
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)	P	N			P	P	N
	Superficial structures & pathologies (incl. Lungs)	P	N			P	P	N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	N			P	P	N
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120234

System: eZono 3000

Transducer: 30CL60

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B + CD)	Other* (Color Power Doppler)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	N			P	P	N
	Abdominal	P	N			P	P	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	N			P	P	N
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)	P	N			P	P	N
	Retroperitoneum	P	N			P	P	N
	female reproductive system and foetus (transcutaneous)	P	N			P	P	N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120234

System: eZono 3000

Transducer: 35CL20

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B + CD)	Other* (Color Power Doppler)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N			N	N	N
	Abdominal	N	N			N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N			N	N	N
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)	N	N			N	N	N
	Retroperitoneum	N	N			N	N	N
	female reproductive system and foetus (transcutaneous)	N	N			N	N	N
Cardiac	Cardiac Adult	N	N			N	N	N
	Cardiac Pediatric	N	N			N	N	N
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K128234

System: eZono 3000

Transducer: 35CL60

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B + CD)	Other* (Color Power Doppler)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	N			P	P	N
	Abdominal	P	N			P	P	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	N			P	P	N
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)	P	N			P	P	N
	Retroperitoneum	P	N			P	P	N
	female reproductive system and foetus (transcutaneous)	P	N			P	P	N
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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

510K K120234

System: eZono 3000

Transducer: currently supported[1]

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler (CD)	Combined (B + CD)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	N			P	P	N
	Abdominal	P	N			P	P	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric (excluding transcranial & neonatal)	P	N			P	P	N
	Small Organ (e.g. testicles, lymph nodes, thyroid)	P	N			P	P	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**	P	N			P	P	N
	Musculo-skeletal **(Superficial)**	P	N			P	P	N
	Intravascular							
	Invasive diagnostic or therapeutic procedures (e.g. biopsies, punctures, free fluid detection, regional anesthesia, vascular access)	P	N			P	P	N
	Retroperitoneum	P	N			P	P	N
	female reproductive system and foetus (transcutaneous)	P	N			P	P	N
	Superficial structures & pathologies	P	N			P	P	N
Cardiac	Cardiac Adult	N	N			N	N	N
	Cardiac Pediatric	N	N			N	N	N
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	N			P	P	N
	Other (Specify)							

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

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

1. supported transducer models are 8LA, 8LA-SC, 12LA, 35CL60, 35CL20 and 30CL60. See their corresponding IFU's.

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

510K K120234