

510(k) Summary

JUL 15 2011

In accordance with 21CFR807.92, the following summary of information is provided;

Date Feb 14th 2011

Submitter: ALPINION MEDICAL SYSTEMS Co., Ltd.
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Korea Republic

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Device Trade Name: E-CUBE 9

Common/Usual Name: Ultrasonic Pulsed Doppler Imaging System

Classification Names System, Imaging, Pulsed Doppler Ultrasonic

Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO
Diagnostic Ultrasound Transducer, 21CFR 892.1570, 90-ITX

Predicate Device(s) K060993 LOGIQ P5/A5 Diagnostic Ultrasound System

Device Description: E-CUBE 9 product is an ultrasound imaging system for medical diagnosis. This product can be used for the applications of abdominal, obstetrics, gynecology, small parts, cardiology, vascular, etc.

The system platform provides optimal patient diagnosis workflow with the 17" wide flat panel display, ergonomic control panel with easy user interface, optimal image quality

Indications For Use: The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult); Peripheral Vascular (PV); and Urology (including prostate).

Technology: E-CUBE 9 employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

E-CUBE 9 has been evaluated for biocompatibility, acoustic output as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. E-CUBE 9 and its application comply with voluntary standards as detailed in this premarket submission. The following quality management system measures were applied to the development of E-CUBE 9:

- ◆ Medical Device Risk Management
- ◆ Requirements Reviews
- ◆ Design Reviews
- ◆ Component Verification
- ◆ Integration Review (System Verification)
- ◆ Performance Testing (System Verification)
- ◆ Safety Testing (Compliance Test)
- ◆ Design Validation

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, E-CUBE 9, did not require clinical studies to support substantial equivalence.

Conclusion: Alpinion Medical Systems Co., Ltd. Considers E-CUBE 9 to be as safe, as effective, and performance is substantially equivalent to the predicate device.

ALPINION MEDICAL SYSTEMS Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA or the requirements will be published in guidance documents.



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

Alpinion Medical Systems Co., Ltd
% Mr. Marc M. Mouser
Engineering Leader & FDA Officer Coordinator Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

JUL 15 2011

Re: K111864
Trade/Device Name: E-CUBE 9 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 2, 2011
Received: June 30, 2011

Dear Mr. Mouser:

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 E-CUBE 9 Ultrasound System, as described in your premarket notification:

Transducer Model Number

SC1-6
C1-6
SVC1-6
VC1-6

L3-12
L3-12H
SP1-5
E3-10

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.

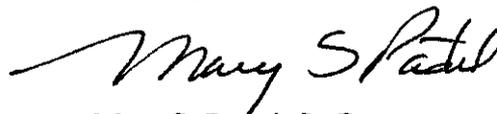
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Lauren Hefner at (301) 796-6881.

Sincerely Yours,



Mary S. Pastel, Sc.D.
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):

Device Name: E-CUBE 9

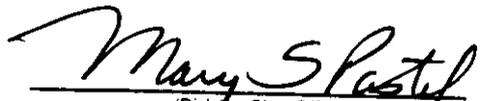
Indications for Use:

The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult); Peripheral Vascular (PV); and Urology (including prostate).

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

510K

K111864

Diagnostic Ultrasound Indications for Use Form

E-CUBE 9 Ultrasound System

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	P	P	P		P	P	P	P	P
Abdominal	P	P	P		P	P	P	P	P
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)	P	P	P		P	P	P	P	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	P	P	P		P	P		P	
Trans-vaginal	P	P	P		P	P		P	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)	P	P	P		P	P	P	P	
Musculo-skeletal (Superficial)	P	P	P		P	P	P	P	
Intravascular									
Cardiac Adult	P	P	P		P	P	P	P	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	P	P	P		P	P	P	P	
Urology (including prostate)	P	P	P		P	P	P	P	

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

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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

Prescription User (Per 21 CFR 801.109)

ALPINION MEDICAL SYSTEMS

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(Division Sign-Off)

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

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K111864

Diagnostic Ultrasound Indications for Use Form

E-CUBE 9 with SC1-6 Transducer

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

Clinical Application	Mode of Operation									
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)	
Ophthalmic										
Fetal	P	P	P		P	P	P	P		
Abdominal	P	P	P		P	P	P	P		
Intra-operative (Specify)										
Intra-operative (Neuro)										
Laparoscopic										
Pediatric	P	P	P		P	P	P	P		
Small Organ (breast, testes, thyroid)										
Neonatal Cephalic										
Adult Cephalic										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Trans-esoph. (non-Card.)										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Intravascular										
Cardiac Adult										
Cardiac Pediatric										
Intravascular (Cardiac)										
Trans-esoph. (Cardiac)										
Intra-cardiac										
Peripheral vessel										
Urology (including prostate)	P	P	P		P	P	P	P		

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

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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E-3

510K *Kill 861*

Diagnostic Ultrasound Indications for Use Form

E-CUBE 9 with C1-6 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	P	P	P		P	P	P	P	
Abdominal	P	P	P		P	P	P	P	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

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

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Prescription User (Per 21 CFR 801.109)

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510K K111864

Diagnostic Ultrasound Indications for Use Form

E-CUBE 9 with SVC1-6 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	P	P	P		P	P	P	P	P
Abdominal	P	P	P		P	P	P	P	P
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	P
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

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

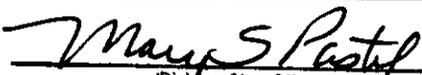
* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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510K K111864

Diagnostic Ultrasound Indications for Use Form

E-CUBE 9 with VC1-6 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	P	P	P		P	P	P	P	P
Abdominal	P	P	P		P	P	P	P	P
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	P
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

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

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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

Prescription User (Per 21 CFR 801.109)

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E-6

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111864

Diagnostic Ultrasound Indications for Use Form

E-CUBE 9 with L3-12 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)	P	P	P		P	P	P	P	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)	P	P	P		P	P	P	P	
Musculo-skeletal (Superficial)	P	P	P		P	P	P	P	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	P	P	P		P	P	P	P	
Urology (including prostate)									

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* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Diagnostic Ultrasound Indications for Use Form

E-CUBE 9 with L3-12H Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P		P	
Small Organ (breast, testes, thyroid)	P	P	P		P	P		P	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)	P	P	P		P	P		P	
Musculo-skeletal (Superficial)	P	P	P		P	P		P	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	P	P	P		P	P		P	
Urology (including prostate)									

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* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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

Prescription User (Per 21 CFR 801.109)

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

510K *K111864*

Diagnostic Ultrasound Indications for Use Form

E-CUBE 9 with SP1-5 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal	P	P	P		P	P	P	P	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)									
Intravascular									
Cardiac Adult	P	P	P		P	P	P	P	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

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* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Diagnostic Ultrasound Indications for Use Form

E-CUBE 9 with E3-10 Transducer

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

Clinical Application	Mode of Operation								
	B	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	P	P	P		P	P		P	
Trans-vaginal	P	P	P		P	P		P	
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (Conventional)									
Musculo-skeletal (Superficial)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P		P	

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

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

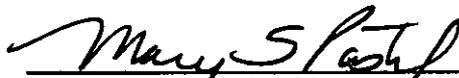
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