K101605

AUG 31 2010

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Esaote Europe B.V.
Philipsweg 1
Maastricht 6227AJ
The Netherlands

Contact Person: Allison Scott, RAC
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ascott@ansongroup.com

Date: March 22, 2010

807.92(a)(2)

Trade Name:	MyLabOne Ultrasound System	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulse Doppler imaging system	892.1550
	Ultrasonic pulsed echo imaging system	892.1560
	Diagnostic ultrasonic transducer	892.1570
Classification Number:	90IYN, 90IYO, 90ITX	

807.92(a)(3)

Predicate Device(s)

K083882	MyLabFive	Esaote Europe B.V.
K092058	NanoMaxx	SonoSite, Inc.

Additional substantial equivalence information is provided in the following substantial equivalence comparison table.

807.92 (a)(4)

Device Description

The MyLabOne is a battery operated, portable ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Amplitude Doppler (AD), Tissue Enhancement Imaging (TEI), Color Flow Mapping (CFM) and Pulse Wave Doppler.
The MyLabOne is equipped with a LCD Color Display. The LCD Display includes touch screen technology for a simple and intuitive activation of functions and data entry for patient information and screen annotations.
The MyLabOne can drive phased (PA), convex (CA) and linear array (LA) probes.
The MyLabOne is equipped with an internal Hard Disk and with an optional external DVD-RW disk drive that can be used for image storage. Data can also be stored directly to external archiving media (hard-disk, PC, server) via a LAN/USB port. Optional accessory devices available for the MyLabOne include a monochrome or color page printer, a desk stand (for use on a desk or cart) and a mobile trolley equipped with four swiveling wheels and peripheral holder.

807.92(a)(5)

Intended Use(s)

Esaote's **MyLabOne** is an arm-held ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Obstetrics/Gynaecology, Transvaginal, Transrectal, Pediatric, Intraoperative Abdominal, and Other: Urology. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

Technological Characteristics

Esaote believes that the MyLabOne is substantial equivalent to Esaote's MyLabFive product (K083882) and SonoSite's Nanomaxx product (K092058).

- Clinical uses for which the MyLabOne is designed are equivalent to those cleared for the Esaote MyLabFive and the SonoSite NanoMaxx.
- The MyLabOne, the Esaote MyLabFive and the SonoSite NanoMaxx are designed to meet the IEC60601-1 and the IEC60601-2-37 safety requirements.
- The MyLabOne, the Esaote MyLabFive and the SonoSite NanoMaxx provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.
- The MyLabOne, the Esaote MyLabFive and the SonoSite NanoMaxx provide a similar measurements and analysis package, with equal accuracy and precision.
- The MyLabOne, the Esaote MyLabFive and the SonoSite NanoMaxx have digital storage capabilities, including Network connectivity.
- The MyLabOne, the Esaote MyLabFive and the SonoSite NanoMaxx are designed to be powered by battery when no main power is available.
- The MyLabOne image modes are available on other FDA cleared ultrasound systems, for instance the Esaote MyLabFive and Sonosite NanoMaxx.

807.92(b)(1)

Non-Clinical Testing

Verification and validation tests have been conducted in accordance with design controls per CFR 820.30.

The system has been designed to meet the following standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-37
- ISO 10993-1
- AIUM/NEMA UD-3 – Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2 – Acoustic Output Measurement Standard for Diagnostic Ultrasound

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Esaote Europe B.V.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services
1394 25th Street NW
BUFFALO MN 55313

AUG 31 2010

Re: K101605
Trade/Device Name: MyLabOne
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: August 18, 2010
Received: August 19, 2010

Dear Mr. Job:

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 MyLabOne, as described in your premarket notification:

Transducer Model Number

SL3323
SL3116
SC3121
SC3123
SC3421
SE3123

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 Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

K101605

510(k) Number (if known): K101605

Device Name: MyLabOne

Indications for Use:

Esaote's MyLabOne is an arm-held ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Obstetrics/Gynaecology, Transvaginal, Transrectal, Pediatric, Intraoperative Abdominal and Other: Urology.

The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

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

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101605

MyLabOne

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal/Obstetrics/Gyn	N	N	N		N	N	N		N	4
Abdominal	N	N	N		N	N	N		N	4
Intraoperative (Abdominal)	N	N	N		N	N	N		N	4
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	4
Small Organ [1]	N	N	N		N	N	N		N	4
Neonatal Cephalic	N	N	N		N	N	N		N	4
Adult Cephalic	N	N	N		N	N	N		N	4
Cardiac [2]	N	N	N		N	N	N		N	4
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	N	N	N		N	N	N		N	4
Transvaginal	N	N	N		N	N	N		N	4
Transurethral										
Intravascular										
Peripheral Vascular (including vascular access)	N	N	N		N	N	N		N	4
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4
Other (Urological)	N	N	N		N	N	N		N	4

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

Additional Comments:

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] XView

Prescription Use Only (Per 21 CFR 801 Part D)
Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)

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

510K K101605

SL3323

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal/Obstetrics/Gyn										
Abdominal	N	N	N		N	N	N		N	4
Intraoperative (Abdominal)	N	N	N		N	N	N		N	4
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	4
Small Organ [1]	N	N	N		N	N	N		N	4
Neonatal Cephalic	N	N	N		N	N	N		N	4
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular (including vascular access)	N	N	N		N	N	N		N	4
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4
Other (Urological)										

The SL3323 probe is to be cleared via this submission

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

Additional Comments:

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] XView

Prescription Use Only (Per 21 CFR 801 Part D)
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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101605

SL3116

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal/Obstetrics/Gyn										
Abdominal										
Intraoperative (Abdominal)	N	N	N		N	N	N		N	4
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	4
Small Organ [1]	N	N	N		N	N	N		N	4
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular (including vascular access)	N	N	N		N	N	N		N	4
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4
Other (Urological)										

The SL3116 probe is to be cleared via this submission

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

Additional Comments:

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] XView

Prescription Use Only (Per 21 CFR 801 Part D)
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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101605

SC3121

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal/Obstetrics/Gyn	N	N	N		N	N	N		N	4
Abdominal	N	N	N		N	N	N		N	4
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	4
Small Organ [1]										
Neonatal Cephalic	N	N	N		N	N	N		N	4
Adult Cephalic										
Cardiac [2]	N	N	N		N	N	N		N	4
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular (including vascular access)	N	N	N		N	N	N		N	4
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4
Other (Urological)	N	N	N		N	N	N		N	4

The SC3121 probe is to be cleared via this submission

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

Additional Comments:

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] XView

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101665

SC3123

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal/Obstetrics/Gyn										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	4
Small Organ [1]	N	N	N		N	N	N		N	4
Neonatal Cephalic	N	N	N		N	N	N		N	4
Adult Cephalic										
Cardiac [2]	N	N	N		N	N	N		N	4
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular (including vascular access)	N	N	N		N	N	N		N	4
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4
Other (Urological)										

The SC3123 probe is to be cleared via this submission

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

Additional Comments:

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] XView

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

510K K101605

SC3421

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal/Obstetrics/Gyn	N	N	N		N	N	N		N	4
Abdominal	N	N	N		N	N	N		N	4
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	4
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular (including vascular access)	N	N	N		N	N	N		N	4
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4
Other (Urological)	N	N	N		N	N	N		N	4

The SC3421 probe is to be cleared via this submission

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

Additional Comments:

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] XView

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101605

SE3123

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal/Obstetrics/Gyn	N	N	N		N	N	N		N	4
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	N	N	N		N	N	N		N	4
Transvaginal	N	N	N		N	N	N		N	4
Transurethral										
Intravascular										
Peripheral Vascular (including vascular access)										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	N	N	N		N	N	N		N	4

The SE3123 probe is to be cleared via this submission

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

Additional Comments:

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] XView

Prescription Use Only (Per 21 CFR 801 Part D)
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