510(k) Summary of Safety and Effectiveness

JAN 26 2012

1. Identifying information

Manufacturer	TELEMED
Address	Dariaus ir Gireno str. 42 Vilnius LT-02189 Lithuania
Telephone	+370-5 2106272 +370-5 2106273
Fax	+370-5 2306733
E-mail	info@telemed.lt yury@telemed.lt
Contact	Yury Sokolov / Engineering Manager
Name of Device	LogicScan 64 / LogicScan 128

2. Class and Predicate Information

Classification Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	PIN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasonic Transducer	892.1570	ITX

Common Name	Ultrasound imaging system	
Propietary Name	LogicScan	
Class	Regulatory Class II	
Predicate Device	SAMSUNG MEDISON CO., LTD	
	MySono U5 Diagnostic Ultrasound System	K100186
	SonoAce R7 Diagnostic Ultrasound System	K112646

3. Performance Standards

The **LogicScan** family has been designed to meet the following:

Safety and EMC Requirements for Medical Equipment:

IEC 60601-1: 2000, Part 1: General requirements for safety.

IEC 60601-1-2: 2001, Part 1: General requirements for basic safety and essential performance, 2.Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-1-2: 2001, Part 1: General requirements for basic safety and essential performance, 2.Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-1-2: 2001, Part 1: General requirements for basic safety and essential performance, 2.Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-1-2: 2001, Part 1: General requirements for basic safety and essential performance, 2.Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-1-4: 1996, Part 1: General Requirements for Safety, 4.Collateral Standard: Programmable Electrical Medical Systems

IEC 60601-2-37: 2007-08 Particular requirements for the basic safety and essential

performance of ultrasonic medical diagnostic and monitoring equipment
NEMA UD 2-2004: 2003, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD 3-2004: 2004, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
AIUM MUS: 2002, Medical Ultrasound Safety
ISO-10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, 2003
ISO-10993-5, Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity , 1999
ISO-10993-10, Biological Evaluation of Medical Devices Part 10: Tests for irritation and delayed-type hypersensitivity, 2002
ISO-10993-11, Biological Evaluation of Medical Devices Part 11: Tests for systemic toxicity, 2006
IEC 62304: 2006 Medical device software – Software life cycle processes
ISO 14971:2007 Medical devices -- Application of risk management to medical devices

Essential Requirements of Council directive 93/42/EEC (Medical Device Directive)

The system's acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

4. Indication for Use

LogicScan 128 / LogicScan 64 ultrasound imaging systems are intended to be used for applications in cardiac (adult), fetal, abdominal, pediatric, small organ, transrectal, neonatal cephalic, peripheral vessel and musculo-skeletal (conventional and superficial). It is possible to provide diagnostic information outside of an imaging lab, including at the bedside systems, for navigated medical application, in operating rooms/critical care units.

5. Device Description

LogicScan 128 / LogicScan 64 color diagnostic systems are intended for the multipurpose ultrasound examinations, based on electronic linear and convex scanning.

LogicScan 128 / LogicScan 64 is a combination of proprietary hardware and software that has been designed for real-time imaging and is intended to be a basic diagnostic tool. The system is based on a modular and flexible architecture allowing for both mobile and stationary (installed) configurations. The system is designed for imaging with transducer ranges of 2 to 12 MHz.

The devices referenced in this submission represent a transportable, software-controlled, diagnostic ultrasound system with accessories.

USB 2.0 connection between the beamformer and PC is a novel feature for ultrasound systems.

The **LogicScan 128 / LogicScan 64** only contains the hardware and firmware, everything else (e.g. ultrasound software, database) is located on a standard PC that is connected to the **LogicScan 128 / LogicScan 64** via USB 2.0. Minimum requirements are given for the PC. The probes are connected to the **LogicScan 128 / LogicScan 64**. All sonograms are saved on the PC and can there be evaluated, printed and archived. The **Echo Wave II** software was especially designed for the **LogicScan 128 / LogicScan 64**. Software able to reside in a Windows-based PC.

The **LogicScan 128 / LogicScan 64** can be used together with the appropriate probes for the entire

ultrasound diagnostic (2MHz to 12MHz probes). Two probes can work simultaneously for **LogicScan 128 2Z** modifications.

Imaging Modes

- B
- B+B
- 4B
- B+M
- M
- Color Doppler (CFM)
- Power Doppler (PDI)
- Directional Power Doppler (DPDI)
- Pulse Wave Doppler (PWD)
- B+PWD (Duplex)
- B+CFM/PDI/DPDI+PWD (Triplex)
- HPRF(**LogicScan 128**)
- Tissue Harmonic Imaging (THI) (**LogicScan 128**)

The devices included in this submission are as follows:

LogicScan 128 EXT-1Z / EXT-2Z ultrasound system utilizing as hardware and firmware an ultrasound engine contained in a small stand alone enclosure for connection to a host PC via a USB port with internal power supply;

LogicScan 128 CEXT-1Z is a compact version of **LogicScan 128 EXT-1Z** with internal medical grade power supply;

LogicScan 128 INT-1Z / INT-2Z ultrasound systems utilizing as hardware and firmware an ultrasound engine contained in a small enclosure for insertion to a host PC (to a drive bays);

A probe, 128 element convex array, at a central ultrasonic frequency of approximately 3.5MHz, model **C3.5/60/128Z**.

A probe, 128 element linear array at a central ultrasonic frequency of approximately 9 MHz, model **HL9.0/40/128Z**.

A probe, 128 element convex array at a central ultrasonic frequency of approximately 6.5 MHz, model **PV6.5/10/128Z**.

A biplane probe BiopSee, combination of:

- 128 element convex array at a central ultrasonic frequency of approximately 6.5 MHz, model **BIPC6.5/10/128Z**
- 128 element linear array at a central ultrasonic frequency of approximately 7.5 MHz, model **BIPL7.5/70/128Z**

LogicScan 64 FLT-1T ultrasound system utilizing as hardware and firmware an ultrasound engine contained in a small stand alone enclosure for connection to a host PC via a USB port;

A probe, 64 element convex array, at a central ultrasonic frequency of approximately 3.5 MHz, model **C3.5/60/64**.

A probe, 64 element linear array at a central ultrasonic frequency of approximately 8.0 MHz, model **HL9.0/40/64**.

A probe, 64 element convex array at a central ultrasonic frequency of approximately 6.5 MHz, model **PV6.5/10/64**.

6. General Safety and Effectiveness

The **LogicScan 128 / LogicScan 64** Ultrasound Systems are similar to currently distributed ultrasonic pulsed echo imaging systems.
There are no technological characteristics or features or indications for use in this Submission that are not previously evaluated and approved in the predicate devices, nor are there such technologies, features and indications for use not commonly used in the practice of diagnostic ultrasound.
The **LogicScan** Ultrasound Systems and its accessories are designed for compliance to all applicable medical devices safety standards, as referenced in DECLARATION OF CONFORMITY (Appendix 05). Prior release for manufacturing, all such devices, so designed, are tested and determined to be in full compliance with acoustic output, biocompatibility, cleaning and disinfection effectiveness. No additional clinical testing is required, as the indications for use are not a novel indication as shown by the predicate devices in Section 1.5 Predicate Device Comparison.
The **LogicScan** has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

7. Patient Contact Materials

The materials of probes, coming in contact with patient are:

- Silicone Rubber
- Acrylonitrile Butadien Styrene (ABS)
- Polyphenylsulfone (PPSU)

Standard for the biological evaluation:
ISO-10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, 2003
ISO-10993-5, Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity , 1999
ISO-10993-10, Biological Evaluation of Medical Devices Part 10: Tests for irritation and delayed-type hypersensitivity, 2002
ISO-10993-11, Biological Evaluation of Medical Devices Part 11: Tests for systemic toxicity, 2006

8. Software

The **LogicScan 128 / LogicScan 64** systems contain the hardware and software which collect and pro-processes 'rough" data and send it via USB 2.0 connection to a Windows® based PC. The main application software is **Echo Wave** II software running on the PC, it is receiving data, processing and showing image/data on the screen. The main user interface shows an ultrasound image, controls and drop-out menus. The ultrasound images and calculated/measured data can be stored in memory.

9. Conclusion

In accordance with the FDA and based on the information provided in this Premarket notification, TELEMED concludes that the **LogicScan 128 / LogicScan 64** are safe and effective and substantially equivalent to predicate devices described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Yury Sokolov
Engineering Manager
TELEMED
Dariaus ir Gireno str. 42
LT-02189 VILNIUS
LITHUANIA

JAN 2 6 2012

Re: K113184
Trade/Device Name: LogicScan 64/LogiScan 128
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: October 28, 2011
Received: October 28, 2011

Dear Mr. Sokolov:

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 DUS 6000 Digital Ultrasonic Imaging System, as described in your premarket notification:

Transducer Model Number

Probes for LogicScan 64	Probes for LogicScan 128
Convex array C3.5/60/64	Convex array C3.5/60/128Z
Linear array HL9.0/40/64	Linear array HL9.0/40/128Z
Convex array PV6.5/10/64	Convex array PV6.5/10/128Z
	BiopSee BIPC6.5/10/128 BIPL7.5/70/128

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, Ph.D. at (301) 796-6881.

Sincerely Yours,

Mary S Pastel

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

Indications for Use

510(k) Number (if known): **K113184**

Device Name: **LogicScan 64 / LogicScan 128**

Indications For Use:

The LogicScan 64 / LogicScan 128 systems and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The applications are:

cardiac (adult), fetal, abdominal, pediatric, small organ, transrectal, neonatal cephalic, peripheral vessel and musculo-skeletal (conventional and superficial).

It is possible to provide diagnostic information outside of an imaging lab, including at the bedside systems, for navigated medical application, in operating rooms/critical care units.

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

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113184

1.3 Indications for Use

All indications for use of subject devices and probes are identified in the table forms:

System LogicScan 64		Fetal*, Abdominal*, Pediatric*, Small Organ* (Breast, Thyroid, Testicles), Neonatal Cephalic*, Musculo-skeletal* (Conventional), Musculo-skeletal* (Superficial), Cardiac Adult*, Peripheral vessel*	Table 1.3-1
Transducers	C3.5/60/64	Fetal*, Abdominal*, Cardiac Adult*	Table 1.3-2
	HL9.0/40/64	Pediatric*,Musculo-skeletal* (Conventional), Musculo-skeletal* (Superficial), Peripheral vessel* Small Organ* (Breast, Thyroid, Testicles)*	Table 1.3-3
	PV6.5/10/64	Pediatric *,Neonatal Cephalic*, Peripheral vessel*	Table 1.3-4
System LogicScan 128		Fetal*, Abdominal*, Pediatric*, Small Organ* (Breast, Thyroid, Testicles), Neonatal Cephalic*, Musculo-skeletal* (Conventional), Musculo-skeletal* (Superficial), Cardiac Adult*, Peripheral vessel*	Table 1.3-5
Transducers	C3.5/60/128Z	Fetal*, Abdominal*, Cardiac Adult*	Table 1.3-6
	HL9.0/40/128Z	Pediatric*,Musculo-skeletal* (Conventional), Musculo-skeletal* (Superficial), Peripheral vessel*, Small Organ* (Breast, Thyroid, Testicles)	Table 1.3-7
	PV6.5/10/128Z	Pediatric *,Neonatal Cephalic*, Peripheral vessel*	Table 1.3-8
	BIPC6.5/10/128Z BIPL7.5/70/128Z	Transrectal*, Intraoperative* (include Needle Guidance)	Table 1.3-9

*Including Imaging for needle guidance

Mary S Pastel

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

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Diagnostic Ultrasound Indications for Use Form

System: LogicScan 64

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

Table 1.3-1

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Note 1	Note 2,3
	Abdominal	N	N	N		N	Note 1	Note 2,3
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2,3
	Small Organ (specify)	N	N	N		N	Note 1	Note 2,3
	Neonatal Cephalic	N	N	N		N	Note 1	Note 2,3
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (**Conventional**)	N	N	N		N	Note 1	Note 2,3
	Musculo-skeletal (**Superficial**)	N	N	N		N	Note 1	Note 2,3
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult	N	N	N		N	Note 1	Note 2,3
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2,3
	Other (specify)							

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

Note 1 - Combined Modes: Color+B, Power+B,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

Mary S Pastel

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

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Diagnostic Ultrasound Indications for Use Form **Table 1.3-2**

System: LogicScan 64 **Transducer:** Convex array C3.5/60/64

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

Table 1.3-6

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Note 1	Note 2,3
	Abdominal	N	N	N		N	Note 1	Note 2,3
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult	N	N	N		N	Note 1	Note 2,3
	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 Appendix E

Note 1 - Combined Modes: Color+B, Power+B,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

Mary S Pastel

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Diagnostic Ultrasound Indications for Use Form

System: LogicScan 64 **Transducer:** Linear array HL9.0/40/64

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

Table 1.3-3

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2,3
	Small Organ (specify)	N	N	N		N	Note 1	Note 2,3
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal **(Conventional)**	N	N	N		N	Note 1	Note 2,3
	Musculo-skeletal **(Superficial)**	N	N	N		N	Note 1	Note 2,3
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2,3
	Other (specify)							

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

Note 1 - Combined Modes: Color+B, Power+B,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
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Diagnostic Ultrasound Indications for Use Form

System: LogicScan 64 **Transducer:** Convex array PV6.5/10/64

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

Table 1.3-4

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2,3
	Small Organ (specify)							
	Neonatal Cephalic	N	N	N		N	Note 1	Note 2,3
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2,3
	Other (specify)							

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

Note 1 - Combined Modes: Color+B, Power+B,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

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Diagnostic Ultrasound Indications for Use Form **Table 1.3-5**

System: LogicScan 128

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 (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Note 1	Note 2,3,4
	Abdominal	N	N	N		N	Note 1	Note 2,3,4
	Intraoperative (specify)	N				N	Note 1	Note 2,5
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2,3,4
	Small Organ (specify)	N	N	N		N	Note 1	Note 2,3,4
	Neonatal Cephalic	N	N	N		N	Note 1	Note 2,3,4
	Adult Cephalic							
	Trans-rectal	N				N	Note 1	Note 2,5
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (**Conventional**)	N	N	N		N	Note 1	Note 2,3,4
	Musculo-skeletal (**Superficial**)	N	N	N		N	Note 1	Note 2,3,4
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult	N	N	N		N	Note 1	Note 2,3,4
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2,3,4
	Other (specify)							

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

Note 1 - Combined Modes: Color+B, Power+B,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
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Diagnostic Ultrasound Indications for Use Form

System: LogicScan 128 **Transducer:** Convex array C3.5/60/128Z

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

Table 1.3-6

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Note 1	Note 2,3,4
	Abdominal	N	N	N		N	Note 1	Note 2,3,4
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)№							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult	N	N	N		N	Note 1	Note 2,3,4
	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 Appendix E

Note 1 - Combined Modes: Color+B, Power+B,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

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510K: K113184

Diagnostic Ultrasound Indications for Use Form

System: LogicScan 128 **Transducer:** Linear array HL9.0/40/128Z

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

Table 1.3-7

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2,3,4
	Small Organ (specify)	N	N	N		N	Note 1	Note 2,3,4
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal **(Conventional)**	N	N	N		N	Note 1	Note 2,3,4
	Musculo-skeletal **(Superficial)**	N	N	N		N	Note 1	Note 2,3,4
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2,3,4
	Other (specify)							

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

Note 1 - Combined Modes: Color+B, Power+B,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

Mary S Pastel

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

510K k 113184

Diagnostic Ultrasound Indications for Use Form

System: LogicScan 128 **Transducer:** Convex array PV6.5/10/128Z

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

Table 1.3-8

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2,3,4
	Small Organ (specify)							
	Neonatal Cephalic	N	N	N		N	Note 1	Note 2,3,4
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2,3,4
	Other (specify)							

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

Note 1 - Combined Modes: Color+B, Power+B,

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Diagnostic Ultrasound Indications for Use Form

System: Logic Scan 128 **Transducer:** BiopSee BIPC6.5/10/128 BIPL7.5/70/128

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

Table 1.3-9

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)	**N**				**N**	**Note 1**	**Note 2,5**
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	**N**				**N**	**Note 1**	**Note 2,5**
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (specify)							
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 Appendix E

Note 1 - Combined Modes: Color+B, Power+B,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

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