FUJIFILM
Fujifilm Medical Systems, USA

FEB - 8 2011 K110202

510(k) Summary
FUJIFILM Diagnostic Ultrasound System
FAZONE CB

Date: January 6, 2011

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, CT, 06902, USA

Contact Person:

Name: Katherine Y. Choi, RAC
Title: Regulatory Affairs Specialist
Telephone: (203) 602-3568
Facsimile: (203) 363-3950

Identification of the Candidate Device:

Proprietary/Trade Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB
Common Name: Diagnostic Ultrasound System
Device Class: Class 2
Review Panel: Radiology
Classification Information:

Classification Name	CFR Section	Product Codes
Ultrasonic Pulsed Doppler Imaging System	21 CFR 892.1550	90 IYN
Ultrasonic Pulsed Echo Imaging System	21 CFR 892.1560	90 IYO
Diagnostic Ultrasonic Transducer	21 CFR 892.1570	90 ITX

I. INDICATIONS FOR USE

The system is intended for use by a qualified physician for ultrasound evaluation of Fetal/obstetric, gynecological, Abdominal (renal, GYN/Pelvic), Pediatric, Small organ (thyroid, breast, testes, etc), Adult & Neonatal Cephalic, Trans-vaginal, Trans-cranial, Musculoskeletal (conventional & superficial), Cardiac-Adult/Pediatric/Fetal, Pelvic, Peripheral vascular, and harmonic tissue.

II. DEVICE DESCRIPTION

The candidate device, FUJIFILM Diagnostic Ultrasound System FAZONE CB, is a general purpose ultrasound diagnostic imaging equipment, which features the compact design suitable for easy transport. The FAZONE CB system generally includes a portable CB main unit, battery, and ultrasound probes. The FAZONE CB compatible ultrasound probes are connected directly to the CB main unit. The control panel of the CB main unit utilizes a touch panel for ease of use providing a virtual keyboard. Optional parts and other system components – for example, external monitor, printer, keyboard, etc. - can be connected to the CB main unit. The CB cart (optional) provides

a docking station for the CB main unit and accommodates optional parts and other system components when they are connected to the CB main unit. The CB main unit can be used without the CB cart.

III. SUMMARY OF STUDIES

The FUJIFILM Diagnostic Ultrasound System FAZONE CB was evaluated in accordance with following safety and performance requirements in addition to the applicable quality system regulations:

IEC 60601-1	Medical electrical equipment - Part 1: General requirements for safety
IEC 60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility
IEC 60601-2-37	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	Medical device software – Software life cycle processes
IEC 62366	Medical devices - Application of usability engineering to medical devices
ISO 10993	Biological evaluation of medical devices
DICOM	Digital Imaging and Communications in Medicine (DICOM)
ISO 14971	Medical devices – Application of risk management to medical devices

No clinical test was conducted.

IV. SUBSTANTIAL EQUIVALENCE

The FUJIFILM Diagnostic Ultrasound System FAZONE CB is substantially equivalent to the following device:

Legally Marketed Device	510(k) #
ZONARE z.one *Ultra* Ultrasound System	K101091

The candidate and marketed devices utilize similar technology and materials, comparable safety and effectiveness features, and they are similar in design and construction. The Indications for Use and labeling are similar and our labeling contains the required Cautions, Warnings and Contraindications consistent to those required for similar marketed device.

V. CONCLUSION

The FUJIFILM Diagnostic Ultrasound System FAZONE CB is substantially equivalent to the legally marketed device and conforms to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Fujifilm Medical Systems USA, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

FEB - 8 2011

Re: K110202
Trade/Device Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: ITX, IYN, and IYO
Dated: January 21, 2011
Received: January 24, 2011

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 FUJIFILM Diagnostic Ultrasound System FAZONE CB, as described in your premarket notification:

Transducer Model Number

FZT E9-4 (Endo-Cavity Probe)
FZT L10-5 (Linear Probe)
FZT P4-1c (Phased/Sector Array Probe)
FZT L8-3 (Linear Probe)
FZT P4-1 (Phased Array Probe)
FZT P10-4 (Phased/Sector Array Probe)
FZT C6-2 (Curvilinear Probe)
FZT C9-3 (Curvilinear Probe)
FZT L14-5sp (Linear Probe)
FZT L14-5w (Linear Probe)

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 Paul Hardy at (301) 796-6542.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
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 Statement

510(k) Number (If Known): _____

Device Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Indications for Use:

The system is intended for use by a qualified physician for ultrasound evaluation of Fetal/obstetric, gynecological, Abdominal (renal, GYN/Pelvic), Pediatric, Small organ (thyroid, breast, testes, etc), Adult & Neonatal Cephalic, Trans-vaginal, Trans-cranial, Musculoskeletal (conventional & superficial), Cardiac-Adult/Pediatric/Fetal, Pelvic, Peripheral vascular, and harmonic tissue.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: With All Transducers

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]	N	N	N		N	N	
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N			N	
	Neonatal Cephalic	N	N	N		N	N	
	Adult Cephalic	N	N	N		N	N	
	Trans-rectal							
	Trans-vaginal	N	N	N		N	N	
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	
	Musculo-skeletal (Superficial)	N	N	N		N	N	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N[1]	N	N		N	N	
	Cardiac Pediatric	N	N	N		N	N	
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic Imaging (HI)
[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
[4] Abdominal includes renal, GYN/Pelvic

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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 K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: FZT E9-4 (Endo-Cavity Probe)

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]							
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	N	
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-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

[1] Includes B-Mode and Harmonic Imaging (HI)
[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
[4] Abdominal includes renal, GYN/Pelvic

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510K K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: FZT L10-5 (Linear Probe)

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]	N	N	N		N	N	
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	
	Neonatal Cephalic	N	N	N		N	N	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	
	Musculo-skeletal (Superficial)	N	N	N		N	N	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic Imaging (HI)
[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
[4] Abdominal includes renal, GYN/Pelvic

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510K K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: FZT P4-1c (Phase/Sector Array Probe)

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]	N	N	N		N	N	
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	N	N	N		N	N	
	Adult Cephalic/ Trans-cranial	N	N	N		N	N	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N[1]	N	N		N	N	
	Cardiac Pediatric	N	N	N		N	N	
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic Imaging (HI)
[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
[4] Abdominal includes renal, GYN/Pelvic

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

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510K K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: FZT L8-3 (Linear Probe)

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]	N	N	N		N	N	
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	
	Neonatal Cephalic	N	N	N		N	N	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	
	Musculo-skeletal (Superficial)	N	N	N		N	N	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic Imaging (HI)
[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
[4] Abdominal includes renal, GYN/Pelvic

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510K K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: FZT P4-1 (Phase/Sector Array Probe)

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]	N	N	N		N	N	
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	N	N	N		N	N	
	Adult Cephalic/ Tran-cranial	N	N	N		N	N	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	
	Cardiac Pediatric	N	N	N		N	N	
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

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[1] Includes B-Mode and Harmonic Imaging (HI)
[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
[4] Abdominal includes renal, GYN/Pelvic

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510K K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: FZT P10-4 (Phase/Sector Array Probe)

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]	N	N	N		N	N	
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	N	N	N		N	N	
	Adult Cephalic/ Tran-cranial	N	N	N		N	N	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	
	Cardiac Pediatric	N	N	N		N	N	
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

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[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
[4] Abdominal includes renal, GYN/Pelvic

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

Mary S Pastel

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: FZT C6-2 (Curvilinear Probe)

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]	N	N	N		N	N	
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic Imaging (HI)
[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
[4] Abdominal includes renal, GYN/Pelvic

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Mary S Pastel

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Office of In Vitro Diagnostic Device Evaluation and Safe

510K K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: FZT C9-3 (Curvilinear Probe)

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]	N	N	N		N	N	
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	
	Musculo-skeletal (Superficial)	N	N	N		N	N	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic Imaging (HI)
[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
[4] Abdominal includes renal, GYN/Pelvic

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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 K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: FZT L14-5sp (Linear Probe)

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]	N	N	N		N	N	
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	
	Neonatal Cephalic	N	N	N		N	N	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	
	Musculo-skeletal (Superficial)	N	N	N		N	N	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic Imaging (HI)
[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
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510K K110202

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): _____

System Name: FUJIFILM Diagnostic Ultrasound System FAZONE CB

Transducer: FZT L14-5w (Linear Probe)

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler[2]	Combined[3]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal	N	N	N		N	N	
	Abdominal[4]	N	N	N		N	N	
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	
	Neonatal Cephalic	N	N	N		N	N	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	
	Musculo-skeletal (Superficial)	N	N	N		N	N	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic Imaging (HI)
[2] Includes Color Doppler (CD) and Power Doppler (PD)
[3] Includes B+M, B+CD+PWD where CD would represent (CD or PD)
[4] Abdominal includes renal, GYN/Pelvic

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