K990401

OCT 15 1999

510(k) Summary

Fukuda Denshi FF sonic model UF-5800A

General Purpose Ultrasound Scanner with Doppler (UF-5800DU)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR part 807.92.

Submitter:

FUKUDA DENSHI AMERICA CORP.
17725 NE 65th St., Bldg C
Redmond WA 98052
Tel: 425/881-7737
Fax: 425/869-2018

Contact Person:

David J. Geraghty
Regulatory Affairs Manager
FUKUDA DENSHI AMERICA CORP.
17725 NE 65th St., Bldg C
Redmond WA 98052
Tel: 425/881-7737
Fax: 425/869-2018

Date Prepared:

January 20, 1998

Device Name:

Proprietary Name:

Fukuda Denshi FF sonic model UF-5800A General Purpose Ultrasound Scanner with Doppler option (UF-5800DU)

Common Name:

General Purpose Ultrasound Scanner with Doppler Option

Classification Name:

Ultrasonic Pulsed Doppler Imaging System (§892.1550)
Ultrasonic Pulsed Echo Imaging System (§892.1560)
Diagnostic Ultrasonic Transducer (§892.1560)

Legally Marketed Device:

- FUKUDA DENSHI FF sonic model UF-4500 General Purpose Ultrasound Scanner (K922208)
- FUKUDA DENSHI FF sonic model UF-3500 General Purpose Ultrasound Scanner (K955543)
- Medison model SonoAce 4800 (K925582)

Description:

The model UF-5800 is a portable, General Purpose Ultrasound Scanning System. The unit will be marketed as the UF-5800A General Purpose Ultrasound Scanner without Doppler. The addition of the optional UF-5800DU Doppler unit will add black and white Doppler capability to the UF-5800A

This ultrasonic device is designed to project ultrasound waves into body tissue and to present the returned echo information on its gray scale monitor. The resulting information is displayed in M-mode, B-Mode, Doppler (both CW and pulsed) modes, or in combinations of modes on the system's 7 inch diagonal video monitor as a 16 level grayscale or black and white image.

Intended Use:

This device is intended to be used for applications in fetal, abdominal, intraoperative (defined as the abdominal region and periphery), pediatric, small organ (defined as thyroid, breast and testes), cardiac, transrectal, transvaginal, and peripheral vessel scanning. Ultrasonic probes are available to obtain images either from the surface of the skin, transrectally, transvaginally or intraoperatively. The UF-5800A incorporates built-in measurement and calculation packages that are to be used by competent health care professionals. The UF-5800A with optional Doppler (UF-5800DU) is a prescription device intended to by used by or on the order of a physician or similarly qualified health care professional. The UF-5800 is intended to be used in a doctor's office and all hospital environments; ER ICU, CCU, OR, etc. This device is intended to be use on any patient; neonate, pediatric, or adult; where the placement and positioning of the transducer does not interfere with or complicate the treatment of the patient. This device is not intended for home use.

Technological Characteristics

The UF-5800 incorporates a microprocessor in the same manner as the predicate devices. The linear and convex, probes, the same probes available for the Fukuda Denshi predicate device, are applicable to the UF-5800A. The UF-5800A will accept sector probes and, with the Doppler option, the CW Doppler probe in a manner similar to the Medison SonoAce 4800 predicate device. Patient contact materials are biocompatable and identical to the predicate Fukuda Denshi devices.

The technological characteristics do not raise new issues with the safety or efficacy of the device. Any safety issues that may be raised by a software controlled medical device are the same issues already addressed by the predicate devices and are addressed in the system's hazard analysis and in the system validation.

The device's derated acoustic output limits are below the maximums established for Track 1 devices as listed in the "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued September 30, 1997, and restated below:

Use	I_{SPTA3} (Mw/CM^2)	ISPTA3 (Mw/CM^2)	MI
Peripheral Vessel	720	190	1.9
Cardiac	430	190	1.9
Fetal Imaging & Other*	94	190	1.9
Ophthalmic	17	28	0.23

Testing:

Laboratory testing was conducted to validate and verify the FUKUDA DENSHI FF sonic model UF-5800A General Purpose Ultrasound Scanner with Doppler option (UF-5800DU) met all design specifications and is substantially equivalent to the currently marketed FUKUDA DENSHI models UF-4500 and UF-3500 as well as the Medison SonoAce 4800. This testing consisted of the environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. Additional testing was performed to demonstrate compliance with the voluntary NEMA/AIUM "Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment," 1992 and ANSI/AAMI ES1-1993, "safe current limits for electromedical apparatus." Patient contact surfaces were confirmed to be biocompatable and met thermal requirements. Finally, a hazard analysis of the system and its software was performed and testing was conducted to verify the systems overall operation.

Conclusion:

The conclusions drawn from the testing of the FUKUDA DENSHI FF sonic model UF-5800A General Purpose Ultrasound Scanner with Doppler option (UF-5800DU) demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices, the FUKUDA DENSHI models UF-4500 (K92208) and UF-3500 (K955543) or the Medison SonoAce 4800 (K925582).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 1999

Fukuda Denshi America Corporation
c/o Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blv.
Suite 200
Great Neck, NY 11021

Re: K990401
Trade Name: Fukuda Denshi FF sonic UF-5800 General Purpose Ultrasound Scanning System with Doppler
Regulatory Class: II
21CFR892.1550/Procode: 90 IYN
21CFR892.1560/Procode: 90 IYO
21CFR892.1570/Procode: 90 ITX
Dated: August 12, 1999
Received: August 16, 1999

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) 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 sonic UF-5800 General Purpose Ultrasound Scanning System, as described in your premarket notification:

Transducer Model Number

FUT-L104, FUT-L106, FUT-C111, FUT-TV36-5, FUT-TR31-5, FUT-io07, FUT-io03, FUT-io10, FUT-io17, FUT-SM181-35A, FUT-SM121-50A, FUT-SM201-25A, FUT-ID121-25A,

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for David A. Feigal

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Attachment #1

EXHIBIT D
(Revised)

Ultrasound Device Indications Statement

Fill out one form for each ultrasound system or transducer

510(k) Number (if known): K990401

Device Name: Fukuda Denshi model UF-5800 System

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N						B/M	
Abdominal		N	N						B/M	
Intraoperative (Specify)		N	N						B/M	
Intraoperative Neurological										
Pediatric		N	N		N				B/M/D	
Small Organ (Specify)		N	N						B/M	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N				B/M/D	
Transesophageal										
Transrectal		N	N						B/M	
Transvaginal		N	N						B/M	
Intravascular										
Peripheral Vessel		N	N	N					B/M/D	
Laparoscopic										
Musculo-skeletal Conventional		N								
Musculo-skeletal Superficial		N								
Other (specify)										

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

Other Indication or Modes: Small Organ is defined as thyroid, breast, and testes.

Intraoperative is defined as the abdominal region and the periphery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legarra

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K990401

Prescription Use ✓

(Per 21 CFR 801.109)

K990401

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **Fukuda Denshi model UF-5800A w/ FUT-L104 Probe**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		**N**	**N**						**B/M**	
Abdominal		**N**	**N**						**B/M**	
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric		**N**	**N**						**B/M**	
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional		**N**							**B**	
Musculo-skeletal Superficial		**N**							**B**	
Laparoscopic										

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

Other Indication or Modes:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seppman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990401

Prescription Use August 25, 1997
(Per 21 CFR 801.109)

K990401

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **Fukuda Denshi model UF-5800A w/ FUT-L106 Probe**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		**N**	**N**						**B/M**	
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric		**N**	**N**						**B/M**	
Small Organ (Specify)		**N**	**N**						**B/M**	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel		**N**	**N**						**B/M**	
Laparoscopic										
Musculo-skeletal Conventional		**N**							**B**	
Musculo-skeletal Superficial		**N**							**B**	
Laparoscopic										

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

Other Indication or Modes: Small Organ is defined as thyroid, breast, and testes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Jegerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990401

K990401

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **Fukuda Denshi model UF-5800A w/ FUT-C111 Probe**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		**N**	**N**						**B/M**	
Abdominal		**N**	**N**						**B/M**	
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legeros

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990401

Prescription Use (Per 21 CRF 801.109)

K990401

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **Fukuda Denshi model UF-5800A w/ FUT-TV36-5 Probe**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		**N**	**N**						**B/M**	
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jessen

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990401

Prescription Use (Per 21 CRF 801.109)

K990401

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **Fukuda Denshi model UF-5800A w/ FUT-TR31-5 Probe**

Intended Use: Diagnostic ultrasound imaging or fluid Small Organ is defined as thyroid, breast, and testes flow analysis of the human body as follows

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		**N**	**N**						**B/M**	
Transvaginal										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes:.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoffman

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K990401

Prescription Use (Per 21 CRF 801.109)

K990401

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **Fukuda Denshi model UF-5800A w/ FUT-IO07 Probe**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		**N**	**N**						**B/M**	
Abdominal										
Intraoperative (Specify)		**N**	**N**						**B/M**	Abdominal
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes: Intraoperative is defined as the abdominal region and the periphery

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990401

Prescription Use (Per 21 CRF 801.109)

K990401

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **Fukuda Denshi model UF-5800A w/ FUT-IO03 Probe**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		**N**	**N**						**B/M**	
Abdominal										
Intraoperative (Specify)		**N**	**N**						**B/M**	Abdominal
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes. Intraoperative is defined as the abdominal region and the periphery

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jessen

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990401

Prescription Use (Per 21 CRF 801.109)

K990401

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **Fukuda Denshi model UF-5800A w/ FUT-IO10 Probe**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		**N**	**N**						**B/M**	
Abdominal										
Intraoperative (Specify)		**N**	**N**						**B/M**	Abdominal
Intraoperative Neurological										
Pediatric		**N**	**N**						**B/M**	
Small Organ (Specify)		**N**	**N**						**B/M**	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes: Intraoperative is defined as the abdominal region and the periphery.

Small Organ is defined as thyroid, breast, and testes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990401

Prescription Use (Per 21 CRF 801.109)

K990401

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **Fukuda Denshi model UF-5800A w/ FUT-IO17 Probe**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		**N**	**N**						**B/M**	
Abdominal										
Intraoperative (Specify)		**N**	**N**						**B/M**	Abdominal
Intraoperative Neurological										
Pediatric		**N**	**N**						**B/M**	
Small Organ (Specify)		**N**	**N**						**B/M**	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes: Intraoperative is defined as the abdominal region and the periphery

Small Organ is defined as thyroid, breast, and testes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990401

Prescription Use (Per 21 CRF 801.109)

EXHIBIT D
(Revised)

Ultrasound Device Indications Statement

Fill out one form for each ultrasound system or transducer

510(k) Number (if known): K990401

Device Name: Fukuda Denshi model UF-5800 w/ FUT-SM181-35A Probe

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		**N**	**N**						**B/M**	
Abdominal		**N**	**N**						**B/M**	
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		**N**	**N**	**N**					**B/M/D**	
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segroves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990401

Indications Statement revised

Prescription Use ✓
(Per 21 CFR 801.109)

EXHIBIT D
(Revised)

Ultrasound Device Indications Statement

Fill out one form for each ultrasound system or transducer

510(k) Number (if known): K990401

Device Name: Fukuda Denshi model UF-5800 w/ FUT-SM121-50A Probe

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		**N**	**N**						**B/M**	
Abdominal		**N**	**N**						**B/M**	
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric		**N**	**N**						**B/M**	
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		**N**	**N**	**N**					**B/M/D**	
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel		**N**	**N**	**N**					**B/M/D**	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990401

Prescription Use ✓
(Per 21 CFR 801.109)

K990401

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: **Fukuda Denshi model UF-5800A w/ UF-5800DU and FUT-SM201-25A Probe**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		**N**	**N**						**B/M**	
Abdominal		**N**	**N**						**B/M**	
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		**N**	**N**	**N**					**B/M/D**	
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990401

Prescription Use (Per 21 CRF 801.109)

K 990401

EXHIBIT D
(Revised)

Ultrasound Device Indications Statement

Fill out one form for each ultrasound system or transducer

510(k) Number (if known): _____

Device Name: Fukuda Denshi model UF-5800 w/ FUT-ID121-25A Probe

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric					N					
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Laparoscopic										

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

Other Indication or Modes:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Number K990401

Indications Statement revised

Prescription Use ✓
(Per 21 CFR 801.109)