FEB 17 2005

Fukuda Denshi Model UF-850 XTD
Special 510(k) Device Modification

Exhibit B
Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92

The assigned 510(k) number is: K 050363

Submitter:
Fukuda Denshi U.S.A. Inc.
17725 NE 65th St. Building C
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Contact Person:
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Tel: 425-881-7737
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Date Prepared:

Device Name: Fukuda Denshi model 850 XTD Diagnostic Ultrasound System

Common Name General Purpose Ultrasound Scanner with Doppler

Classification: Ultrasound Pulse Doppler Imaging System, 21 CFR 892-1550, 90IYN
Ultrasound Pulse Echo Imaging System, 21 CFR 892-1560, 90-IYO
Diagnostic Ultrasound Transducer, 21 CFR 892-1570, 90-ITX

Marketed Device: Fukuda Denshi model FF sonic UF-750XT Diagnostic Ultrasound System, 510(k) No. K033209 and Fukuda Denshi model FF sonic UF-5800 Ultrasound System with Doppler 510(k) K99040, currently in commercial distribution.

Device Description: The Fukuda Denshi model UF-850 XTD is a full featured general purpose Track III diagnostic ultrasound system. The device consist of a mobile console approximately 19" wide, 31"deep and 53-57" (adjustable) high, that provides digital acquisition, processing and display capabilities. The user interface includes a keyboard, specialized controls and either a color CRT or LCD display.

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Intended Use:

The device is intended to be used for applications in fetal, abdominal, pediatric, small organ (defined as the thyroid, breast and testes), cardiac (adult and pediatric), transvaginal, peripheral vessel and musculo-skeletal (Conventional and Superficial). The UF-850XTD incorporates built-in measurement and calculation packages that are to be used by competent health care professionals. The UF-850XTD is a prescription device intended to be use by or on the order of a physician or similarly qualified healthcare professional. The device is intended to be used 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-850XTD incorporates the same fundamental technology as the predicate device. All probes are modified version of the probes cleared with the predicate. The device has been tested as Track 3 devices per the guidance document:" Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers" Issued September 30th, 1997. The Acoustic Output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 1998. The system will assure that the acoustic output will always stay below the pre-amendment upper limits i.e. Ispta $\leq$720mW/cm^2 and MI $\leq$1.9 (Track 3, Non ophthalmic) All patient contact materials are biocompatible and identical to the predicate Fukuda Denshi device.

The technology characteristics of the FF sonic UF-850XTD do not affect the safety or efficacy of the device. Any safety issues raised by a software controlled medical device are either the same as the issues already addressed by the predicate device or are addressed in the system risk management or in the system validation.

Testing:

Laboratory Testing:
Laboratory testing was conducted to verify that the Fukuda Denshi model UF-850XTD met all design specification and was substantially equivalent to the currently marketed Fukuda Denshi FF sonic model UF-750XT. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility and effectiveness of cleaning and disinfection.

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Acoustic output is measured and calculated according to "Acoustic Output Measuring Standard for Diagnostic Ultrasound Equipment (AUIM 1998)

Applicable Standards
The Fukuda Denshi Model FF sonic UF-750XT conforms to the following Safety Standards:

- NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 1998
- NEMA/AIUM UD 3 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices: 1998
- EN 60601-1-1:2000 Part 1: General Requirements for Safety
- EN 60601-1-2: 2001 Electromagnetic Compatibility
- EN 60601-1-2-37:2001 Particular Requirements for the Safety of Ultrasound Medical Diagnostic and Monitoring Equipment.
- ISO 10993 Biocompatibility
- ISO-14971:2000 Application of Risk Management to Medical Devices

Clinical Test:
No clinical testing was required

Conclusion: The conclusion drawn from the testing of the Fukuda Denshi model UF-850 XT Diagnostic Ultrasound system demonstrates that this device is as safe, as effective and performs as well or better than the current legally marketed predicate device, the Fukuda Denshi model UF-750 XT. (510(k) No.. K033209

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2005

Mr. Larry D. Walker
Regulatory Affairs Manager
Fukuda Denshi U.S.A., Inc.
Seattle Branch
17725 N.E. 65th Street, Building C
REDMOND WA 98052

Re: K050363
Trade Name: Fukuda Denshi Model UF-850XTD Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasound pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: February 10, 2005
Received: February 14, 2005

Dear Mr. Walker:

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 Fukuda Denshi Model UF-850XTD Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

FUT-CG602-5A
FUT-CG505-8A

FUT-LG386-9A
FUT-LG308-16A
FUT-SG162-5A
FUT-SG125-8A
FUT-TVG114-7A

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 898. 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 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small

Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-850XTD Diagnostic Ultrasound System

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)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P	P	P	P	P	B/M/D/C	P	
Abdominal		P	P	P	P	P	P	P	B/M/D/C	P	
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P	P	B/M/D/C		
Small Organ		P	P	P		P	P	P	B/M/D/C		
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P	P	B/M/D/C	P	
Transesophageal											
Transrectal											
Transvaginal		P	P	P		P	P	P	B/M/D/C		
Intravascular											
Peripheral Vessel			P			P	P	P	B/M/D/C		
Laparoscopic											
Musculo-skeletal Conventional		P		P							
Musculo-skeletal Superficial		P		P							
Other (specify)											

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

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (including PWD, CWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050363

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-850XTD with FUT-CG602-5A

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)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	B/M/D/C	P	
Abdominal		P	P	P		P	P	P	B/M/D/C	P	
Intraoperative											
Intraoperative Neurological											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)

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Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K050363

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-850XTD with FUT-CG505-8A

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)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	B/M/D/C		
Abdominal		P	P	P		P	P	P	B/M/D/C		
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P		P	P	P	B/M/D/C		
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050363

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-850XTD with FUT-LG386-9A

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)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P					B/M		
Abdominal		P	P	P							
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P		P	P	P	B/M/D/C		
Small Organ		P	P	P							
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel		P	P	P		P	P	P	B/M/D/C		
Laparoscopic											
Musculo-skeletal Conventional		P		P							
Musculo-skeletal Superficial		P		P							
Other (specify)											

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

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)

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Concurrence of CDHR, Office of Device Evaluation (ODE)

David A. Legassa

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050363

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-850XTD with FUT-LG308-16A

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)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P					B/M		
Abdominal											
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P		P	P	P	B/M/D/C		
Small Organ		P	P	P							
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel		P	P	P		P	P	P	B/M/D/C		
Laparoscopic											
Musculo-skeletal Conventional		P		P							
Musculo-skeletal Superficial		P		P							
Other (specify)											

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

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (PWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)

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Concurrence of CDHR, Office of Device Evaluation (ODE)

David G. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K050363

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-850XTD with FUT-SG162-5A

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)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P	P	P	P	P	B/M/D/C	P	
Abdominal		P	P	P	P	P	P	P	B/M/D/C	P	
Intraoperative											
Intraoperative Neurological											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P	P	B/M/D/C	P	
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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

Other Indications or Modes:

In Combined mode: B = B mode, M = M mode, D = Doppler (including PWD, CWD), C = Color Doppler (including Amplitude Doppler, Color Velocity Doppler)

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Concurrence of CDHR, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050363

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-850XTD with FUT-SG125-8A

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)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P	P	P	P	P	B/M/D/C		
Abdominal		P	P	P		P	P	P	B/M/D/C		
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P	P	B/M/D/C		
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P	P	B/M/D/C		
Transesophageal											
Transrectal											
Transvaginal											
Intravascular											
Peripheral Vessel		P	P	P		P	P	P	B/M/D/C		
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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Concurrence of CDHR, Office of Device Evaluation (ODE)

David A. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K050363

Ultrasound Device Intended Use Form

Fill out one form for each ultrasound system or transducer

Device Name: UF-850XTD with FUT-TVG114-7A

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)	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		P	P	P		P	P	P	B/M/D/C		
Abdominal		P	P	P		P	P	P	B/M/D/C		
Intraoperative											
Intraoperative Neurological											
Pediatric											
Small Organ		P	P	P		P	P	P	B/M/D/C		
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal		P	P	P		P	P	P	B/M/D/C		
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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Concurrence of CDHR, Office of Device Evaluation (ODE)

David A. Hegarty

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Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K050363