

MAY 20 1998

510(k) Summary

New Intended use ... Musculoskeletal Imaging

Fukuda Denshi General Purpose Ultrasound Scanners
UF-3500 (K955543) and UF-4500 (K922208)

K981404

Submitter:

FUKUDA DENSHI AMERICA CORP.
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Redmond WA 98052
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Contact Person:

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

Date Prepared:

March 26, 1998

Device Name:

New Intended Use:

Conventional and Superficial Musculoskeletal Imaging for the

- Fukuda Denshi FF sonic model UF-3500 General Purpose Ultrasound Scanner (K955543) and the
- Fukuda Denshi FF sonic model UF-4500 General Purpose Ultrasound Scanner (K922208)

Common Name:

Conventional and Superficial Musculoskeletal Imaging

Classification Name:

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

Legally Marketed Device:

- ATL model Level 10 HDI Ultrasound System (K961459)
- GE Model LOGIQ 500 (k970901)

Description:

The Fukuda Denshi model UF-4500 (K022208) and the model UF-3500 (K955543) are general-purpose ultrasound systems that have been previously found to be substantially equivalent under the Food and Drug Administration's 510(k) process. These devices have not been changed or modified in any way. All software and hardware, all portions of the device that control the acoustic power out are unchanged.

The addition of both conventional and musculoskeletal imaging as intended uses require no changes to the operating instructions.

Intended Use:

As originally submitted, these devices are 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 (UF-4500 only), transrectal, transvaginal (UF-4500 only), and peripheral vessel scanning. This submission adds conventional and superficial musculoskeletal imaging to both devices.

Both the UF-3500 and the UF-4500 are prescription devices intended to be used by or on the order of a physician or similarly qualified health care professional. Both are intended to be used in a doctor's office and all hospital environments; ER ICU, CCU, OR, etc. These devices are 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. These devices are not intended for home use.

Technological Characteristics

The UF-3500 and UF-4500 incorporate microprocessors in a manner similar to the predicate devices. No changes to the hardware or software that control the device or the acoustic output were required to support the claims for musculoskeletal imaging. Conventional and superficial musculoskeletal imaging is possible with linear probes in B-Mode. Patient contact materials have not changed

Both devices' derated acoustic output limits remain 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:

Skilled sonographers using both the UF-3500 and the UF-4500 obtained images. All imaged were reviewed by a radiologist who rendered findings and clinical impression.

Conclusion:

Based on the anatomical identification of musculoskeletal soft tissues and the diagnostic images obtained from the UF-3500 and the UF-4500, these devices have exhibited the capability of accurately and reproducibly imaging the musculoskeletal structure. Fukuda Denshi has demonstrated through this study that the device is safe and effective in obtaining conventional and superficial musculoskeletal images and is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

David J. Geraghty
Regulatory Affairs Manager
Fukuda Denshi America Corp.
17725 NE 65th Street
Redmond, WA 98052

Re: K981404
Fukuda Denshi Ultrasound Scanners Models
UF-3500 and UF-4500
Dated: March 23, 1998
Received: April 17, 1998
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Geraghty:

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Fukuda Denshi Ultrasound Scanners Models UF-3500 and UF-4500, as described in your premarket notification:

Transducer Model Number

FUT-L104 (5.0 MHz, 60mm)
FUT-L106 (7.5 MHz, 40mm)

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:

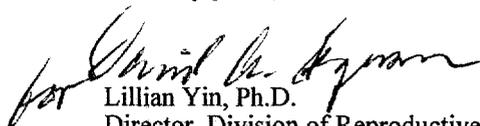
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

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-3500 System

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

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

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

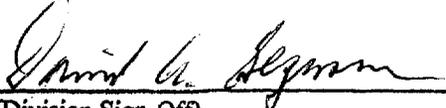
Other Indication or Modes: Intraoperative is defined as the abdominal region and the periphery

Small Organ is defined as thyroid, breast, and testes

Musculo-skeletal Superficial is defined as muscle, tendon, ligament, bursa, and other soft tissue in the vicinity of the shoulder, elbow, wrist, knee, and/or ankle.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K981404

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-3500 w/ FUT-L104 Probe

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|-------------------------------|-------------------|---|--|--|-----|---------------|-------------------|------------------------|--------------------|-----------------|
| | A | B | | | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | P | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | | | | | | | | |
| Small Organ (Specify) | | P | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vessel | | P | | | | | | | | |
| 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

Musculo-skeletal Superficial is defined as muscle, tendon, ligament, bursa, and other soft tissue in the vicinity of the shoulder, elbow, wrist, knee, and/or ankle.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K981404

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-3500 w/ FUT-L106 Probe

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|-------------------------------|-------------------|----------|--|--|-----|---------------|-------------------|------------------------|--------------------|-----------------|
| | A | B | | | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | P | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Specify) | | P | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vessel | | P | | | | | | | | |
| 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

Musculo-skeletal Superficial is defined as muscle, tendon, ligament, bursa, and other soft tissue in the vicinity of the shoulder, elbow, wrist, knee, and/or ankle.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Johnson

 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K9814024

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-4500 System

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

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

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

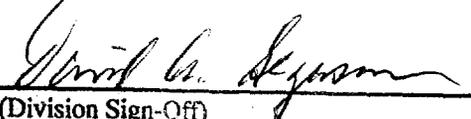
Other Indication or Modes: Intraoperative is defined as the abdominal region and the periphery

Small Organ is defined as thyroid, breast, and testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K081402

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-4500 w/ FUT-L104 Probe

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

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

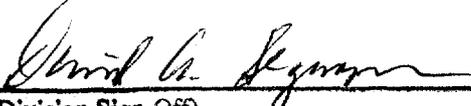
N = new indication; P = previously cleared by FDA; E = added under Appendix E

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

Musculo-skeletal Superficial is defined as muscle, tendon, ligament, bursa, and other soft tissue in the vicinity of the shoulder, elbow, wrist, knee, and/or ankle.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K981404

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-4500 w/ FUT-L106 Probe

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

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

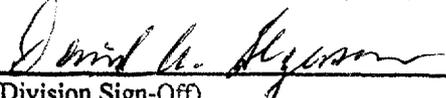
N = new indication; P = previously cleared by FDA; E = added under Appendix E

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Musculo-skeletal Superficial is defined as muscle, tendon, ligament, bursa, and other soft tissue in the vicinity of the shoulder, elbow, wrist, knee, and/or ankle.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number 1981404