K990198

JUN 29 1999

ALLIANCE MEDICAL INC.

Appendix C

510(k) SUMMARY

SUBMITTER: Alliance Medical Inc.
7800 Cote de Liesse
St. Laurent, Quebec
Canada H4T 1G1
Tel. (514)-344-3030
Fax. (514)-344-4440

January 14, 1999

PREPARED BY: James Riedl

CLASSIFICATION NAME: Ultrasonic Pulsed Echo Imaging System, 892.1560 (CLASS II)

COMMON OR USUAL NAME: Ultrasonic Diagnostic System

PROPRIETARY NAME: AMIB7

PREVIOUSLY MARKETED DEVICE TO	-Hitachi EUB-405	K924126
WHICH SUBSTANTIAL EQUIVALENCE	-Aloka SSD-500	K900805
IS BEING CLAIMED:	-Fukada UF-4500	K922208

The AMIB7 is compact, lightweight and completely self-contained (w12" x h10" x l20") portable multipurpose ultrasound scanning system as are the predicate devices. The device can be carried anywhere for diagnostic purposes. The unit may operate from either a power source of 110vac / 220vac or from its' internal battery. A fully charged battery is able to provide the unit with approximately 1.5 hours of continuous operation. The predicate devices do not provide a means for battery operation.

The AMIB7 uses a multi-frequency probe technology to produce high quality images (256 grey scale). The operator can select the best frequency, depending on the probe in use, to optimize near field imaging resolution and far field imaging penetration. The operator can move the focal point deeper through the image to reach the complex focus zone, to provide a better image resolution.

The system features several operating modes, as do the predicate devices, and offers the following exam capabilities: B-mode, M-mode. It is designed to perform Abdominal, Cardiac, and peripheral vascular, Pediatric, Obstetrical/Gynecological, Musculo-skeletal and small parts. The AMIB7 also enables the user to print reports viewed on screen.

The AMIB7 allows the user to set up a wide variety of default parameters for easy operation like the predicate devices mentioned above. A sophisticated package of measurements and calculations (Distance, Area, Circumference, Volume, Heart Rate, Ejection Fraction) are available B and M modes. In obstetric measurements for example, one can use the system equations and pre-programmed comparison tables or can set-up the unit and apply his own tables. The operator of the AMIB7 unit can adjust the depth of the displayed echo The system master gain allows the operator to uniformly control the gain level for all parts of the displayed image. The system Time Gain Compensation (TGC) allows for level adjustment of the echo amplification in near and far field (upper and the lower part of the echographic image).

Appendix C

To simplify the movement of the cursor and the positioning of the caliper during measurements, a trackpad is provided on the control panel. Most of the system functions were also assigned to keyboard "quick keys" for rapid execution by the operator.

The options being offered with this Ultrasonic Diagnostic System are.

- Connections for 1 or 2 probes
- Video Printer (75ohm BNC Interconnections)
- External Monitor (75ohm BNC Interconnections)
- Footswitch
- Probe support (stand)

Since the options or combination of options, as stated above, are available as an integral part of the Ultrasonic Diagnostic System, the AMIB7 will inevitably be offered in various configurations while maintaining the intended use and technological characteristics presented here within.

The AMIB7 Ultrasound does not in any way raise new questions of safety or effectiveness, when used as labeled, in comparison to the predicate devices. The AMIB7s are tested for compliance according to the Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1999

James Riedl
Quality Assurance Director
Alliance Medical, Inc.
7800 Cote De Liesse,
Ville St-Laurent
Montreal H4T 1G1
CANADA

RE: K990198
AMIB7 Ultrasound Diagnostic System
Dated: May 14, 1999
Received: may 28, 1999
Regulatory Class; II
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Riedl:

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 AMIB7 Ultrasonic Diagnostic System, as described in your premarket notification:

Transducer Model Number

AMO61 (Convex, 2.3-6.0 MHz)

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.

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:

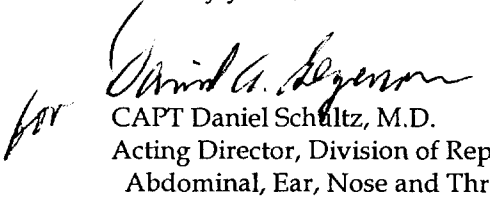
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 Perez at (301) 594-1212.

Sincerely yours,



for CAPT Daniel 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

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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							
Abdominal		N	N							
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N							
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional		N	N							
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: AMI B7 with AM061 Probe (Convex 2.3-6.0 MHz)

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990198