510(k) Summary

For BRODASOUND Model

AL3C34A, AL7L50A, AL3C79B, AL7L24B,
AT3C42B, AT3C52B, AT5L40B, AT3P32A, and AT3P42A

Diagnostic Ultrasound Transducer Assemblies

OCT 15 2007

510(k) Number:	K070195
Submitter:	Broadsound Corporation 5F, No. 31, Shintai Road Jupei City, Hsinchu 30252, Taiwan Tel: 886-3-5539868, Fax: 886-3-5539808
Contact Person:	Jiann-Hwa Jeng, Ph.D., President & CEO
Date Prepared:	August 30, 2007
Device Name:	
Trade Name:	BROADSOUND
Model Name:	AL3C34A, AL7L50A, AL3C79B, AL7L24B AT3C42B, AT3C52B, AT5L40B, AT3P32A, AT3P42A
Common Name:	Diagnostic Ultrasound Transducer Assembly, Ultrasound Imaging Probe, Medical Ultrasound Probe, or Diagnostic Ultrasound Probe
Classification Name:	Transducer, Ultrasonic, Diagnostic
Classification Regulation:	21 CRF 892.1570
Product Code:	90ITX
Class:	II

Device Comparison:

Legally marketed devices for substantial equivalence comparison are listed as following:

Subject Device	Predicate Device		
	510(k) Number	Model Name	Manufacturer
AL3C34A	K900805, K880900	UST-934N-3.5	Aloka Ltd.
AL7L50A	K900805, K880900	UST-5512U-7.5	Aloka Ltd.
AL3C79B	K983879	UST-979-3.5	Aloka Ltd.
AL7L24B	K983879	UST-5524-7.5	Aloka Ltd.
AT3C42B	K002003	C5-2	ATL Ultrasound Inc.
	Marketed product	C4-2	ATL Ultrasound Inc.
AT3C52B	K002003	C5-2	ATL Ultrasound Inc.
AT5L40B	K002003	L7-4	ATL Ultrasound Inc.
AT3P32A	K974269, K961459	Medison P4-2	Medison America, Inc.
	Marketed product	ATL P3-2	ATL Ultrasound Inc.
AT3P42A	K974269, K961459	Medison P4-2	Medison America, Inc.
	Marketed product	ATL P4-2	ATL Ultrasound Inc.

Each of above referenced transducer assemblies is substantially equivalent to its corresponding predicate device, and both of them are very similar to each other in terms of features and use parameters; as well, they are used on the same diagnostic ultrasound systems.

Legally marketed devices that Broadsound replacement transducers are intended to replace with are summarized as following:

Broadsound New Replacement Model	Predicate OEM Transducer Model	Indicated System
AL3C34A	Aloka UST-934N-3.5	Aloka SSD-500
AL7L50A	Aloka UST-5512U-7.5	Aloka SSD-500
AL3C79B	Aloka UST-979-3.5	Aloka SSD-900
AL7L24B	Aloka UST-5524-7.5	Aloka SSD-900
AT3C42B	ATL C4-2	ATL HDI 5000
AT3C52B	ATL C5-2	ATL HDI 5000
AT5L40B	ATL L7-4	ATL HDI 5000
AT3P32A	ATL P3-2	ATL HDI 5000
AT3P42A	ATL P4-2	ATL HDI 5000

Description of Devices:

The above referenced devices are replacement ultrasound transducers used with standard ultrasound systems. Each of them consists of piezoelectric crystals covered with an acoustic lens, a scan head that fits around the lens, a cable with strain relief devices on both ends, and a connector to attach the transducer to the ultrasound console.

The specifications of each transducer assembly are listed as following:

Specification	AL3C34A	AL7L50A	AL3C79B	AL7L24B
Frequency range	5-2 MHz	10-5 MHz	5-2 MHz	10-5 MHz
Array type	Convex	Linear	Convex	Linear
Field of view	60 degree	38 mm	70 degree	42 mm
Element number	72	72	120	120
Pitch	1.0 mm	0.6 mm	0.6 mm	0.375 mm

Specification	AT3C42B	AT3C52B	AT5L40B	AT3P32A	AT3P42A
Frequency range	4-2 MHz	5-2 MHz	7-4 MHz	3-2 MHz	4-2 MHz
Array type	Convex	Convex	Linear	Phased	Phased
Field of view	75 degree	75 degree	40 mm	90 degree	90 degree
Element number	128	128	128	64	64
Pitch	0.4 mm	0.4 mm	0.6 mm	0.32 mm	0.32 mm

Intended Use:

The above referenced Broadsound transducer assemblies are intended for use, with standard ultrasound systems, in diagnostic ultrasound imaging or fluid flow analysis of the human body and to be operated by or under the direction of a physician.

Their specific indications for use are listed as following:

	Model Name	Specific Indications of Use*
1	AL3C34A	Abdominal, Fetal
2	AL7L50A	Small organ, Peripheral vascular
3	AL3C79B	Abdominal, Fetal, Pediatric
4	AL7L24B	Small organ, Peripheral vascular
5	AT3C42B	Abdominal, Fetal, Pediatric
6	AT3C52B	Abdominal, Fetal, Pediatric
7	AT5L40B	Abdominal, Pediatric, Peripheral vascular, Musculo-skeletal
8	AT3P32A	Abdominal, Adult cephalic, Cardiac
9	AT3P42A	Abdominal, Adult cephalic, Cardiac

Characteristics of Technology:

Each of above referenced Broadsound transducer assemblies is substantially equivalent to its corresponding predicate device, and both of them are very similar to each other in terms of features and use parameters; as well, they are used on the same diagnostic ultrasound systems. No new technology is employed on these devices.

Safety Testing:

Electrical, Mechanical, thermal, and biocompatible safety testing were conducted on these devices; the results are included in the submission.

Performance Testing:

Each of above referenced ultrasound transducer assemblies and its corresponding predicate device were tested for acoustic output and found statistically comparable to each other. Performance testing was also conducted and included in the submission.

CE Mark:

All above referenced devices have been granted CE_{0197} mark of European Union by TÜV Rheinland Product Safety GmbH, Germany since April 2006, and the pertinent information is included in the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jiann-Hwa Jeng, Ph.D.
President & CEO
Broadsound Corporation
5F, No.31, Shintai Road
JUPEI CITY HSINCHU 30252
TAIWAN

OCT 15 2007

Re: K070195
Trade/Device Name: BROADSOUND
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: August 31, 2007
Received: September 4, 2007

Dear Dr. Jeng:

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 BROADSOUND, as described in your premarket notification:

Transducer Model Number

AL3C34A	AT3C52B
AL7L50A	AT5L40B
AL3C79B	AT3P32A
AL7L24B	AT3P42A
AT3C42B	

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Ewa Czerska, MD at (240) 276-3666.

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)

Indications For Use Statement

510(k) Number: K070195

Common Name: Diagnostic Ultrasound Transducer Assembly,
Ultrasound Imaging Probe,
Medical Ultrasound Probe, or
Diagnostic Ultrasound Probe

Device Name

Trade Name: BROADSOUND

Model Name: AL3C34A, AL7L50A, AL3C79B, AL7L24B,
AT3C42B, AT3C52B, AT5L40B, AT3P32A, AT3P42A

The above referenced devices are replacement ultrasound transducers intended to be used with standard ultrasound systems in diagnostic ultrasound imaging or fluid flow analysis of the human body and to be operated by or under the direction of a physician.

Their specific indications for use are listed as following:

Model Name		Specific Indications of Use*
1	AL3C34A	Abdominal, Fetal
2	AL7L50A	Small organ, Peripheral vascular
3	AL3C79B	Abdominal, Fetal, Pediatric
4	AL7L24B	Small organ, Peripheral vascular
5	AT3C42B	Abdominal, Fetal, Pediatric
6	AT3C52B	Abdominal, Fetal, Pediatric
7	AT5L40B	Abdominal, Pediatric, Peripheral vascular, Musculo-skeletal
8	AT3P32A	Abdominal, Adult cephalic, Cardiac
9	AT3P42A	Abdominal, Adult cephalic, Cardiac

Prescription Use ___X___ (Part21 CFR801 Subpart D)

Over-The-Counter Use _____ (Part21 CFR801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070195

Diagnostic Ultrasound Indications for Use Form

510(K) Number (if known): K070195
Device Name (transducer): BROADSOUND AL3C34A
Ultrasound System: Aloka SSD 500 series

Indications for Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P						Note 1	
Abdominal		P	P						Note 1	
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; **P** = previously cleared by FDA under K900805 and K880900; **E** = added under Appendix E

Note 1: Combined application includes B/M mode.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070195

Diagnostic Ultrasound Indications for Use Form

510(K) Number (if known): K070195
Device Name (transducer): BROADSOUND AL7L50A
Ultrasound System: Aloka SSD 500 series

Indications for Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P						Note 1	
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA under K900805 and K880900; E = added under Appendix E

Note 1: Combined application includes B/M mode.

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K070195

Diagnostic Ultrasound Indications for Use Form

510(K) Number (if known): K070195
Device Name (transducer): BROADSOUND AL3C79B
Ultrasound System: Aloka SSD 900 series

Indications for Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P						Note 1	
Abdominal		P	P						Note 1	
Intraoperative (specify)										
Pediatric		P	P						Note 1	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA under K983879; E = added under Appendix E

Note 1: Combined application includes B/M mode.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070195

Diagnostic Ultrasound Indications for Use Form

510(K) Number (if known): K070195
Device Name (transducer): BROADSOUND AL7L24B
Ultrasound System: Aloka SSD 900 series

Indications for Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Pediatric										
Small Organ (specify)		P	P						Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P						Note 1	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA under K983879; E = added under Appendix E

Note 1: Combined application includes B/M mode.

Small organ applications: Breast, Testes, Thyroid

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070195

Diagnostic Ultrasound Indications for Use Form

510(K) Number (if known): K070195
Device Name (transducer): BROADSOUND AT3C42B
Ultrasound System: ATL HDI 5000 series

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

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		Note 1	
Abdominal		P	P	P		P	P		Note 2	
Intraoperative (specify)										
Pediatric		P	P	P		P	P		Note 2	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA under K002003; E = added under Appendix E
Note 1: Combined application includes B/M mode.
Note 2: Combined applications include B/M, PWD/Color Doppler, and PWD/ Power Doppler modes.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K070195

Diagnostic Ultrasound Indications for Use Form

510(K) Number (if known): K070195
Device Name (transducer): BROADSOUND AT3C52B
Ultrasound System: ATL HDI 5000 series

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

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		Note 1	
Abdominal		P	P	P		P	P		Note 2	
Intraoperative (specify)										
Pediatric		P	P	P		P	P		Note 2	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; **P** = previously cleared by FDA under K002003; **E** = added under Appendix E
Note 1: Combined application includes B/M mode.
Note 2: Combined applications include B/M, PWD/Color Doppler, and PWD/ Power Doppler modes.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070195

Diagnostic Ultrasound Indications for Use Form

510(K) Number (if known): K070195
Device Name (transducer): BROADSOUND AT5L40B
Ultrasound System: ATL HDI 5000 series

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

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		P	P		Note 1	
Intraoperative (specify)										
Pediatric		P	P	P		P	P		Note 1	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P			Note 1	
Laparoscopic										
Musculo-skeletal		P	P	P		P			Note 1	
Conventional										
Musculo-skeletal Superficial		P	P	P		P				
Other (specify)										

N = new indication; P = previously cleared by FDA under K002003; E = added under Appendix E
Note 1: Combined applications include B/M, PWD/Color Doppler, and PWD/ Power Doppler modes.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices,
510(k) Number K070195

Diagnostic Ultrasound Indications for Use Form

510(K) Number (if known): K070195
Device Name (transducer): BROADSOUND AT3P32A
Ultrasound System: ATL HDI 5000 series

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

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		Note 1	
Abdominal		P	P	P	P	P	P		Note 2	
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		Note 2	
Cardiac		P	P	P	P	P	P		Note 2	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA under K974269 & K961459; E = added under Appendix E
Note 1: Combined application includes B/M mode.
Note 2: Combined applications include PWD/Color Doppler and PWD/ Power Doppler modes..

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070195

Diagnostic Ultrasound Indications for Use Form

510(K) Number (if known): K070195
Device Name (transducer): BROADSOUND AT3P42A
Ultrasound System: ATL HDI 5000 series

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

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		Note 1	
Abdominal		P	P	P	P	P	P		Note 2	
Intraoperative (specify)										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		Note 2	
Cardiac		P	P	P	P	P	P		Note 2	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA under K974269 & K961459; E = added under Appendix E
Note 1: Combined application includes B/M mode.
Note 2: Combined applications include PWD/Color Doppler and PWD/ Power Doppler modes..

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070195