K043524
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510(k) Summary:

JAN 13 2005

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: B-K Medical
Address: Mileparken 34, DK2730 Herlev, Denmark
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Contact person: Villy Braender, Regulatory Manager
Date prepared: 17 December, 2004

Trade name: Ultrasound Scanner Pro Focus 2202
Common name: Diagnostic Ultrasound System
Classification names:

Ultrasonic Pulsed Echo Imaging System	(90 IYO, CFR 892.1560)
Ultrasonic Pulsed Doppler Imaging System	(90 IYN, CFR 892.1560)
Diagnostic Ultrasonic Transducer	(90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:
B-K Medical Ultrasound Scanner Type 2400, **K024236 (JAN17 2003)**

Device description:

Pro Focus 2202 supports the following scanning modes and combinations thereof:
B-mode, M-mode, PWD mode, CFM mode.
An optional ECG signal can be superimposed the ultrasound information in all modes and mode combinations.
The system can perform simple geometric measurements, and perform calculations in the areas of Vascular, Urology, Cardiology and OB/GYN applications.
The system can guide biopsy- and puncture needles.
An optional 3-D unit can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.

Transducers
Transducers are linear and convex arrays and mechanical sector.
The patient contact materials are biocompatible.
All transducers used together with Pro Focus 2202 are Track 3 transducers.

Acoustic output
The system controlling the Acoustic Output in Pro Focus 2202 is the same as the system in 2400.
The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta $\leq$ 720 mW/cm^2 and MI $\leq$ 1.9 (Track 3, non ophthalmic).
The Thermal Index values are maximum 6.0, i.e. TI $\leq$ 6.0

Clinical measurement accuracy.
Clinical measurements and calculations are described and accuracies are provided in the User Guide.

Thermal, mechanical and electrical safety.
The scanner Pro Focus 2202 has been tested by a recognized, Certified Body.

Acoustic Output Reporting

The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 30, 1997"

Intended use.

2202 intended uses are contained within 2400-intended uses:

	Predicate device: Ultrasound scanner Type 2400 **K024236 (JAN17 2003)**	Submitted device: Ultrasound scanner Pro Focus 2202
Modes of operation	B, M, PWD, CFM 1) and combinations. Tissue harmonic imaging	B, M, PWD,CW, CFM 1) and combinations. Tissue and contrast harmonic imaging
Intended use(clinical application)	Abdominal Cardiac Fetal (incl Obstetrics) Intraoperative Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Musculo-skeletal	Abdominal Cardiac Fetal (incl Obstetrics) Intraoperative Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Musculo-skeletal
Features	ECG (not monitoring)	ECG (not monitoring) 3D

1) CFM= Color Flow Mapping=Color Doppler and Amplitude Doppler.

Technological characteristics compared to the predicate device.

The predicate device has the same major technological characteristics as the subject device described above.

Minor differences consist: Modified processor and operating system, modified mechanical outline and 3D imaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

Mr. Villy Brænder
Regulatory Manager
B-K Medical A/S
Mileparken 34
Herlev 34, DK 2730
DENMARK

Re: K043524
Trade Name: Ultrasonic Scanner Pro Focus 2202
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: December 17, 2004
Received: December 31, 2004

Dear Mr. Brænder:

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 Ultrasonic Scanner Pro Focus 2202, as described in your premarket notification:

Transducer Model Number

1850
8661
8662

8803
8811

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,

Nancy C Brogdon

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

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

System: 2202

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	Tissue- and contrast harmonic imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify 1)	Continous Wave)
Ophthalmic										
Fetal		P	P	P	P	P	P		P	
Abdominal		P	P	P	P	P	P		P	
Intraoperative (specify)		P	P	P	P	P	P		P	
Intraoperative Neurological		P	P	P	P	P	P		P	
Pediatric		P	P	P	P	P	P		P	
Small Organ (specify)		P	P	P	P	P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P	
Transesophageal										
Transrectal		P	P	P	P	P	P		P	
Transvaginal		P	P	P	P	P	P		P	
Transurethral		P	P	P	P	P	P		P	
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		P	
Musculo-skeletal Superficial		P	P	P	P	P	P		P	
Other (specify)										

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

Additional Comments: 1) B+M, B+D, B+C, B+D+C. B mode includes Tissue-and Contrast Harmonic Imaging. D is PWD, C is Color Doppler. Fetal is often called Obstetrics

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

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

510(k) Number K043524

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2202

Transducer: 1850 (with interchangeable probes 8539,6004,6005)

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	P						
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA(K002085); E= added under Appendix E

*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Intraoperative: Rectum, Urethra, Urinary bladder,

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

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

510(k) Number K043524

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2202
Transducer: 8661

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Amplitude Doppler
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P 1)	P
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	P 1)	P
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: 1)) Mode combinations: B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043524

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2202
Transducer: 8662

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify 1)	Amplitude Doppler
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify 2)	P	P	P		P	P	P
	Intra-operative (Neuro)	P	P	P		P	P	P
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: 1) Mode combinations: B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)
2)Intraoperative: Gall bladder

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and Radiological Devices
510(k) Number K042524

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2202
Transducer: 8803

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	Harmonic imaging	Color Doppler	Combined (Specify)	Amplitude Doppler
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P 1)	P
	Abdominal	P	P	P	P	P	P 1)	P
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P 1)	P
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	P 1)	P
	Cardiac Pediatric	P	P	P	P	P	P 1)	P
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: 1)) Mode combinations: B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043524

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2202
Transducer: 8811

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	Harmonic imaging	Color Doppler	Combined (Specify 1)	Amplitude Doppler
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify 2)	P	P	P	P	P	P	P
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Specify 3)	P	P	P	P	P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P	P	P	P	P
	Musculo-skel. (Superficial)	P	P	P	P	P	P	P
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: 2)Intraoperative: Breast, liver, pancreas, biliary system
3)Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes
1) mode combinations: B, B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)

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Prescription Use (Per 21 CFR 801.109)

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510(k) Number K043524