DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 17, 2016

BK Medical ApS
% Ms. Karen Provencher
Sr. Regulatory Specialist
Mileparken 34
Herlev 2730
DENMARK

Re: K161960
Trade/Device Name: bk2300
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: July 19, 2016
Received: July 20, 2016

Dear Ms. Provencher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161960

Device Name
bk2300

Indications for Use *(Describe)*
The system is a diagnostic ultrasound imaging system used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow analysis and puncture and biopsy guidance.
The clinical applications and exam types include: Fetal (including Obstetrics), Abdominal, Pediatric, Small Organ (also known as Small Parts), Adult Cephalic (also known as Adult Trans cranial), Neonatal Cephalic, Intra-operative, Intra-operative (Neuro), Trans rectal, Trans-vaginal, Trans-urethral, Musculo-skeletal (Conventional and Superficial), Cardiac Adult, Trans-esophageal Cardiology, and Peripheral Vessel (also known as Peripheral Vascular).

Contraindications:
• The 2300 Ultrasound System is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.
• The Cardiac Adult application is not intended for direct use on the heart.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

System: bk2300

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD 4)	Tissue Harmonic Imaging	CHI 5)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal	P	P	P	P	P	P	P	P		P	P 3)
Abdominal	P	P	P	P	P	P	P	P		P	P 3)
Intra-operative (Specify)	P	P	P	P	P	P	P	P		P	P 3)
Intra-operative (Neuro)	P	P	P	P	P	P	P	P		P	P 3)
Laparoscopic											
Pediatric	P	P	P	P	P	P	P	P		P	P 3)
Small Organ (Specify)	P	P	P	P	P	P	P	P		P	P 3)
Neonatal Cephalic	P	P	P	P	P	P	P	P		P	P 3)
Adult Cephalic	P	P	P	P	P	P	P	P		P	P 3)
Trans-rectal	P	P	P	P	P	P	P	P		P	P 3)
Trans-vaginal	P	P	P	P	P	P	P	P		P	P 3)
Trans-urethral	P	P	P	P	P	P	P	P		P	P 3)
Trans-esoph. (non-Card.)											
Musculo-skel. (Conventional)	P	P	P	P	P	P	P	P		P	P 3)
Musculo-skel. (Superficial)	P	P	P	P	P	P	P	P		P	P 3)
Intra-luminal											
Cardiac Adult	P	P	P	P	P	P	P	P		P	
Cardiac Pediatric											
Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	N		N	
Peripheral vessel	P	P	P	P	P	P	P	P		P	P 2) P 3)
Other (Specify)											

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Vector Flow Imaging (VFI): Previously cleared in K143298
3) Elastography: Previously cleared in K143298
4) Continuous Wave Doppler (CWD/CW): Previously cleared in K143298
5) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9027 (T7P2m)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD 2)	Tissue Harmonic Imaging	CHI 3)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative (Neuro)											
Laparoscopic											
Pediatric											
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 17)											
Other (Specify)											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. Cardiac	N	N	N	N	N	N	N	N		N	
Other (Specify)											
Peripheral vessel)											
Other (Specify)											
Other (Specify)											
Other (Specify)											

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

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Continuous Wave Doppler (CWD/CW): Previously cleared in K143298
3) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9002 (9C2)

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

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

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Elastography: Previously cleared in K143298

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9009 (X18L5s)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	CHI	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)	P	P	P		P		P	P		P	
Intra-operative (Neuro)											
Laparoscopic											
Pediatric											
Small Organ (Specify)	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 Adult)											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel	P	P	P		P		P	P		P	

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk 2300

Transducer: 9011 (13L4w)

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

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

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Small Organ: thyroid, breast, testes, penis, parathyroid, salivary glands, lymph nodes.
3) Elastography: Previously cleared in K143298

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: bk2300 (bk5000)

Transducer: 9015 (I14C5I)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	CHI 4)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify) 3)	P	P	P		P	P	P	P		P	P 2)
Intra-operative (Neuro)											
Laparoscopic											
Pediatric	P	P	P		P	P	P	P		P	P 2)
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 Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel											

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Elastography: Previously cleared in K143298
3) Inter-operative: Liver, Biliary, Pancreas, Kidney, Stomach, Breast
4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: bk2300 (bk5000)

Transducer: 9016 (I14C5T)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	CHI 4)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal	P	P	P		P	P	P	P		P	P 2)
Intra-operative (Specify) 3)	P	P	P		P	P	P	P		P	P 2)
Intra-operative (Neuro)											
Laparoscopic											
Pediatric											
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 Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel											

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Elastography: Previously cleared in K143298
3) Inter-operative: Liver, Biliary, Pancreas, Kidney
4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300 (bk3000, bk5000)

Transducer: 9018 (E14C4t)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	CHI 3)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative (Neuro)											
Laparoscopic											
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic)											
Adult Cephalic)											
Trans-rectal	P	P	P		P	P	P	P		P	P2)
Trans-vaginal	P	P	P		P	P	P	P		P	P2)
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skel. (Conventional)											
Musculo-skel. (Superficial)											
Intra-luminal											
Other (Specify)											
Cardiac Adult)											
Cardiac Pediatric)											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel)											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Elastography: Previously cleared in K143298
3) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9019 (E10C4)

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

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

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)

2) Elastography: Previously cleared in K143298

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9022 (10L2w)

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

Clinical Application Specific (Tracks I & III)	B	M	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
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 Adult									
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel	P	P	P	P	P	P		P	P 2), P 3)
Other (Specify)									

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Elastography: Previously cleared in K143298
3) Vector Flow Imaging (VFI): Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: bk2300
Transducer: 9023 (6C2s)

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

Clinical Application Specific (Tracks I & III)	B	M	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal	P	P	P	P	P	P		P	P 2), P 3)
Abdominal	P	P	P	P	P	P		P	P 2), P 3)
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P	P	P	P		P	P 2), P 3)
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 Adult									
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel									
Other (Specify)									

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Elastography: Previously cleared in K143298
3) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: bk2300 (bk3500, bk5000)

Transducer: 9024 (I12C5b)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	CHI 4)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify 2)	P	P	P		P	P	P	P		P	P 3)
Intra-operative (Neuro)											
Laparoscopic											
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic)											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skel. (Conventional)	P	P	P		P	P	P	P		P	P 3)
Musculo-skel. (Superficial)											
Intra-luminal											
Other (Specify)											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel	P	P	P		P	P	P	P		P	P 3)

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Intra-operative: Liver, Biliary, Pancreas, Kidney
3) Elastography: Previously cleared in K143298
4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: bk2300 (bk5000)

Transducer: 9026 (X12C4)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	CHI 4)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify 2)	P	P	P		P	P	P	P		P	P 3)
Intra-operative (Neuro)											
Laparoscopic											
Pediatric											
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 Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel											

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Intra-operative: Pancreas, Kidney, Liver
3) Elastography: Previously cleared in K143298
4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9032 (8L2)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	CHI 4)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative (Neuro)											
Laparoscopic											
Pediatric	P	P	P		P	P	P	P		P	P 3)
Small Organ (Specify 2)	P	P	P		P	P	P	P		P	P 3)
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skel. (Conventional)	P	P	P		P	P	P	P		P	P 3)
Musculo-skel. (Superficial)	P	P	P		P	P	P	P		P	P 3)
Intra-luminal											
Other (Specify)											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel	P	P	P		P	P	P	P		P	P 3)

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Small Organ: Thyroid, Breast, Testes
3) Elastography: Previously cleared in K143298
4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9040 (6C2)

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

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

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)

2) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk 2300 (bk3000, bk5000)

Transducer: 9048 (E14CL4b)

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

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

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Elastography: Previously cleared in K143298
3) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9051 (14L3)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	Contrast Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative (Neuro)											
Laparoscopic											
Pediatric	P	P	P		P		P	P		P	P3)
Small Organ (Specify 2)	P	P	P		P		P	P		P	P3)
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skel. (Conventional)	P	P	P		P		P	P		P	P3)
Musculo-skel. (Superficial)	P	P	P		P		P	P		P	P3)
Intra-luminal											
Other (Specify)											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel	P	P	P		P		P	P		P	P3) P4)
Other (Specify)											

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
   B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Small Organ: Breast, Thyroids, Testes
3) Elastography: Previously cleared in K143298
4) Vector Flow Imaging (VFI): Previously cleared in K143298

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: bk2300 (bk3000, bk5000)

Transducer: 9052 (20R3)

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

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

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9062 (N13C5)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	Contrast Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify 2)	P	P	P		P		P	P		P	P3)
Intra-operative (Neuro)	P	P	P		P		P	P		P	P3)
Laparoscopic											
Pediatric	P	P	P		P		P	P		P	P3)
Small Organ (Specify)											
Neonatal Cephalic	P	P	P		P		P	P		P	P3)
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skel. (Conventional)											
Musculo-skel. (Superficial)											
Intra-luminal											
Other (Specify)											
Cardiac Adult)											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel)											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Inter-operative: Gallbladder
3) Elastography: Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300 (bk5000)

Transducer: 9063 (N11C5s)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	CHI 3)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify 2)	P	P	P		P	P	P	P		P	
Intra-operative (Neuro)	P	P	P		P	P	P	P		P	
Laparoscopic											
Pediatric											
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 Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel											

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Intra-operative: Gall Bladder
3) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: bk2300 (bk5000)

Transducer: 9066 (I12C4f)

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	CHI 3)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify 2)	P	P	P		P	P	P	P		P	P 4)
Intra-operative (Neuro)											
Laparoscopic											
Pediatric											
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 Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Other (Specify)											
Peripheral vessel											

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Intra-operative: Liver, Biliary, Pancreas, Kidney, Stomach
3) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298
4) Elastography: Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300 (bk3000)

Transducer: 9067 (E14C4)

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

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

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)

2) Elastography: Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9070 (18L5)

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

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

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Small Organ: thyroid, breast, testes, superficial anatomy.
3) Elastography: Previously cleared in K143298

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9077 (5P1)

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

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

N= new indication; P= previously cleared by FDA in K140428; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B includes Tissue Harmonic Imaging, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)

2) Continuous Wave Doppler (CWD/CW): Previously cleared in K143298

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

bk medical

Analogic Ultrasound Group

7. 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR 807.92

A. Submitter's information

Name:	BK Medical ApS
Address:	Mileparken 34 Herlev 2730 Denmark
FDA Establishment Owner / Operator Number:	9680269
Contact person:	Karen Provencher
Phone:	978-326-4668
Fax:	978-977-6809
Manufacturer:	BK Medical ApS Mileparken 34 Herlev 2730 Denmark

B. Device Name:

Trade/Proprietary Name:	bk2300
Common Name:	Ultrasound system
Classification name:	Doppler Imaging System and Ultrasonic Pulsed Echo
Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	IYN, IYO, ITX
Regulation Number:	892.1550, 892.1560, and 892.1570
Device Classification:	2
Submission type:	Traditional 510(k)

C. Substantial Equivalence:

This submission is a Traditional 510(k) device modification as described in the FDA's Guidance document entitled, "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications". In support of this Traditional 510(k), BK Medical ApS has provided certification of compliance to 21 CFR §820.30 Design Control requirements. Design validation testing was performed to ensure that the Ultrasound Scanner System bk2300 with modifications meets design specifications. The Ultrasound Scanner System bk2300 with modifications has been compared to the legally marketed predicate devices as cleared through K151910 (October 5, 2015), K132346 (January 10, 2014), K140729 (5/23/2014), and K103629 (2/2/2011) respectively and is found to be substantially equivalent.

This proposed device is identical to the identified predicates except for the proposed integration of software and transducer for the following:

- Electrocardiograph (ECG) display of the electrical and muscular activity of the heart. Impulses from the heart are relayed via electrodes to the system and appear as a waveform on the screen measurement display.
- Trans-esophageal visualization of the heart (and other organs) with an ultrasound transducer. The transducer is inserted into the esophagus through the mouth to visualize a plane of the heart through the esophageal wall.

D. Device Description/Indications for Use:

The Ultrasound Scanner System bk2300 is a multi-purpose mobile, software controlled diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms.

The transducers are all multi-frequency transducers including:

- Phased Linear Array
- Convex/Curved linear array.

The interaction with the patients is dependent upon the transducer type which may be:

- Surface contact,
- Intra-operative, or
- contact through Endocavity

when used in locations as described by the indications for use.

The function of the ultrasound scanner system and its transducers is to acquire primary or secondary harmonic ultrasound echo data and display it in the scanning modes.

Indications for Use:

The system is a diagnostic ultrasound imaging system used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow analysis and puncture and biopsy guidance.
The clinical applications and exam types include: Fetal (including Obstetrics), Abdominal, Pediatric, Small Organ (also known as Small Parts), Adult Cephalic (also known as Adult Trans cranial), Neonatal Cephalic, Intraoperative, Intraoperative (Neuro), Trans rectal, Trans-vaginal, Transurethral, Musculoskeletal (Conventional and Superficial), Cardiac Adult, Trans-esophageal Cardiology, and Peripheral Vessel (also known as Peripheral Vascular).

Contraindications:

- The 2300 Ultrasound System is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.
- The Cardiac Adult application is not intended for direct use on the heart.

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Options:

- Vector Flow Imaging (VFI) module is available: Color Flow Mapping (CFM) imaging mode with the ability to visualize both the axial and the transverse velocity.
- Alternate power source (battery) solution.
- RF wireless function with the ability to transmit for printing and archive connectivity purposes.
- Electrocardiograph display of the electrical and muscular activity of the heart. Impulses from the heart are relayed via electrodes to the system and appear as a waveform on the screen.

E. Technological Characteristics

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the currently marketed predicate devices.

F. Summary of Non-clinical Test/Performance Testing - Bench:

BK Medical ApS believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria was met. Results of this testing have confirmed that the proposed device is substantially equivalent to the predicate devices and is suitable for the labeled indications for use.

The system complies with the following voluntary standards:

- EN IEC 62304:2006 + AC:2008 Medical Device Software Life-Cycle Processes
- EN 60601-1:2006 (Ed.3)+AC:2010, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 (Ed.3) + Cor1:2006 + Cor2:2010)
- EN 60601-1-2:2007+AC:2010, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007)
- EN 60601-2-37:2008 Medical electrical equipment – Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007)
- EN 62359:2010 Ultrasonic - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields (IEC 62359:2010)