



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

BK Medical ApS
% Mrs. Randi Hauerberg
Regulatory Affairs Lead Manager
Mileparken 34
DK-2730 Herlev
DENMARK

October 5, 2015

Re: K151910
Trade/Device Name: Ultrasound Scanner System bk2300
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: September 10, 2015
Received: September 21, 2015

Dear Mrs. Hauerberg:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a large, semi-transparent watermark of the FDA logo.

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

Indications for Use

510(k) Number (if known)

K151910

Device Name

Ultrasound Scanner System bk2300

Indications for Use (Describe)

Ultrasound scanner and transducers for B, Tissue and Contrast Harmonic Imaging, M, PWD, CWD, Color Doppler, Vector Flow Imaging and combined mode imaging and Elastography.

Signal Analysis.

Guidance of biopsy needles, geometrical measurements and calculation of parameters. And optimal 3-D unit can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.

An optional Vector Flow Imaging (VFI) module: Color Flow Mapping (CFM) imaging mode with the ability to visualize both the axial and the transverse velocity.

An optional RF wireless function with the ability to wireless transmit for printing and archive connectivity purpose.

Clinical Applications:

- Fetal (Sometimes called Obstetrics)
- Abdominal
- Intra-operative
- Intra-operative (Neuro) (sometimes called Neuro Surgical)
- Pediatrics
- Small Organ (Sometimes called Small Parts)
- Neonatal Cephalic (Cephalic is sometimes called trans-cranial)
- Adult Cephalic (Cephalic is sometimes called trans-cranial)
- Trans-rectal
- Trans-vaginal
- Trans-urethral
- Musculo-skeletal (Conventional)
- Musculo-skeletal (Superficial)
- Cardiac Adult
- Peripheral Vessel (Sometimes called Peripheral Vascular)

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)

PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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.

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)	P	P	P	N	P	N	P	P		P	N 25)
Abdominal 3)	P	P	P	N	P	N	P	P		P	N 25)
Intra-operative (Specify 4)	P	P	P	N	P	N	P	P		P	N 25)
Intra-operative (Neuro 5)	P	P	P	N	P	N	P	P		P	N 25)
Laparoscopic 6)											
Pediatric 7)	P	P	P	N	P	N	P	P		P	N 25)
Small Organ (Specify 8)	P	P	P	N	P	N	P	P		P	N 25)
Neonatal Cephalic 9)	P	P	P	N	P	N	P	P		P	N 25)
Adult Cephalic 10)	P	P	P	N	P	N	P	P		P	N 25)
Trans-rectal 11)	P	P	P	N	P	N	P	P		P	N 25)
Trans-vaginal 12)	P	P	P	N	P	N	P	P		P	N 25)
Trans-urethral 13)	P	P	P	N	P	N	P	P		P	N 25)
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	P	P	P	N	P	N	P	P		P	N 25)
Musculo-skel. (Superficial 16)	P	P	P	N	P	N	P	P		P	N 25)
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)	P	P	P	N	P	N	P	P		P	
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	P	P	P	N	P	N	P	P		P	N 24 N 25)
Other (Specify 24)											N
Other (Specify 25)											N)

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. Tissue Harmonic Imaging.

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.

Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

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

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

(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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9002

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)	E	E	E		E		E	E		E	E 25)
Abdominal 3)	E	E	E		E		E	E		E	E 25)
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)	E	E	E		E		E	E		E	E 25)
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	E	E	E		E		E	E		E	E 25)
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	E	E	E		E		E	E		E	E 25)
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9011

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)	E	E	E		E		E	E		E	E 25)
Small Organ (Specify 8)	E	E	E		E		E	E		E	E 25)
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	E	E	E		E		E	E		E	E 25)
Musculo-skel. (Superficial 16)	E	E	E		E		E	E		E	E 25)
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	E	E	E		E		E	E		E	E 25)
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9015

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)	E	E	E		E	E	E	E		E	E 25)
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)	E	E	E		E	E	E	E		E	E 25)
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9016

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

Clinical Application Specific (Tracks I & III)	Modes											
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other	
Ophthalmic												
Fetal 2)												
Abdominal 3)	E	E	E		E	E	E	E		E	E 25)	
Intra-operative (Specify 4)	E	E	E		E	E	E	E		E	E 25)	
Intra-operative (Neuro 5)												
Laparoscopic 6)												
Pediatric 7)												
Small Organ (Specify 8)												
Neonatal Cephalic 9)												
Adult Cephalic 10)												
Trans-rectal 11)												
Trans-vaginal 12)												
Trans-urethral 13)												
Trans-esoph. (non-Card.) 14)												
Musculo-skel. (Conventional 15)												
Musculo-skel. (Superficial 16)												
Intra-luminal 17)												
Other (Specify 18)												
Cardiac Adult 19)												
Cardiac Pediatric 20)												
Trans-esoph. (Cardiac 21)												
Other (Specify 22)												
Peripheral vessel 23)												
Other (Specify 24)												
Other (Specify 25)												P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2. Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9018

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)	P	P	P		P	E	P	P		P	N25)
Trans-vaginal 12)	P	P	P		P	E	P	P		P	N25)
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											N

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9019

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)	E	E	E		E		E	E		E	E 25)
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)	E	E	E		E		E	E		E	E 25)
Trans-vaginal 12)	E	E	E		E		E	E		E	E 25)
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.

Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9022

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	E	E	E		E		E	E		E	E 24) E 25)
Other (Specify 24)											P
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9023

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)	P	P	P		P	E	P	P		P	E 25)
Abdominal 3)	P	P	P		P	E	P	P		P	E 25)
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)	P	P	P		P	E	P	P		P	E 25)
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2. Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9024

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)	E	E	E		E	E	E	E		E	E 25)
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	E	E	E		E	E	E	E		E	E 25)
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	E	E	E		E	E	E	E		E	E 25)
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2. Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9026

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)	E	E	E		E	E	E	E		E	E 25)
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9032

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)	E	E	E		E	E	E	E		E	E 25)
Small Organ (Specify 8)	E	E	E		E	E	E	E		E	E 25)
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	E	E	E		E	E	E	E		E	E 25)
Musculo-skel. (Superficial 16)	E	E	E		E	E	E	E		E	E 25)
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	E	E	E		E	E	E	E		E	E 25)
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9040

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)	E	E	E		E	E	E	E		E	
Abdominal 3)	E	E	E		E	E	E	E		E	
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	E	E	E		E	E	E	E		E	
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2. Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9048

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)	E	E	E		E	E	E	E		E	E 25)
Trans-vaginal 12)	E	E	E		E	E	E	E		E	E 25)
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9051

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)	P	P	P		P		P	P		P	N 25)
Small Organ (Specify 8)	P	P	P		P		P	P		P	N 25)
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	P	P	P		P		P	P		P	N 25)
Musculo-skel. (Superficial 16)	P	P	P		P		P	P		P	N 25)
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	P	P	P		P		P	P		P	N 24) N 25)
Other (Specify 24)											N
Other (Specify 25)											N

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9052

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)		E									
Trans-vaginal 12)		E									
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2. Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

(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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9062

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)	P	P	P		P		P	P		P	N25)
Intra-operative (Neuro 5)	P	P	P		P		P	P		P	N25)
Laparoscopic 6)											
Pediatric 7)	P	P	P		P		P	P		P	N25)
Small Organ (Specify 8)											
Neonatal Cephalic 9)	P	P	P		P		P	P		P	N25)
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											N

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. 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: 9063

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)	P	P	P		P	P	P	P		P	
Intra-operative (Neuro 5)	P	P	P		P	P	P	P		P	
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

System: bk2300

Transducer: 9066

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)	E	E	E		E	E	E	E		E	E 25)
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD, C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9067

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)	P	P	P		P		P	P		P	E 25)
Trans-vaginal 12)	P	P	P		P		P	P		P	E 25)
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2. Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9070

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)	P	P	P		P		P	P		P	E 25)
Small Organ (Specify 8)	P	P	P		P		P	P		P	E 25)
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	P	P	P		P		P	P		P	E 25)
Musculo-skel. (Superficial 16)	P	P	P		P		P	P		P	E 25)
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	P	P	P		P		P	P		P	E 25)
Other (Specify 24)											
Other (Specify 25)											P

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI)
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW)
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2. Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. 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)

Attachment 1:

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

Transducer: 9077

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

Clinical Application Specific (Tracks I & III)	Modes										
	B	M	PWD	CWD 26)	Tissue Harmonic Imaging	CHI 27)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)	P	P	P	N	P		P	P		P	
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)	P	P	P	N	P		P	P		P	
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)	P	P	P	N	P		P	P		P	
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											
Other (Specify 25)											

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. Tissue Harmonic Imaging.

- 24) Vector Flow Imaging (VFI).
- 25) Elastography.
- 26) Continuous Wave Doppler (CWD/CW).
- 27) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI).

The numbering in the table above refers to comments and history provided, if considered relevant. Comment 1 is provide in the table below. The rest of the comments are provided in Attachment 2.
Please do observe that the numbering of the comments from 1 to 27 are fixed to make the document more consistent meaning that comment 1 is provided here below and the rest of the comments are provided in the attachment 2 if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. 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)

510(k) Summary:

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

Submitters name: BK Medical

Address: Mileparken 34, DK-2730 Herlev, Denmark

Phone: +45 44528100

Fax: +45 44528199

Contact person: Randi Hauerberg, Regulatory Affairs Lead Manager

Date prepared: July 28, 2015

Trade name: Ultrasound Scanner System bk 2300

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 892.1550)

Diagnostic Ultrasonic Transducer (90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:

B-K Medical Ultrasound Scanner bk2300, K143298

Device description:

Ultrasound scanner and transducers for B, Tissue and Contrast Harmonic Imaging, M, PWD, CWD, Color Doppler, Vector Flow Imaging and combined mode imaging and Elastography.

Signal Analysis.

Guidance of biopsy needles, geometrical measurements and calculation of parameters. And optimal 3-D unit can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.

An optional Vector Flow Imaging (VFI) module: Color Flow Mapping (CFM) imaging mode with the ability to visualize both the axial and the transverse velocity.

An optional RF wireless function with the ability to wireless transmit for printing and archive connectivity purpose.

Transducers

All the transducers in this submission have previously been cleared.

There are no changes to the physical design of the transducers

There are no changes to the patient contact materials. All patient contact materials are biocompatible.

All transducers used together with bk2300 are Track 3 transducers.

Acoustic output

The system controlling the Acoustic Output in the modified bk2300 is the same as the system in the predicate device Pro Focus 2202. The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. $Ispta \leq 720 \text{ mW/cm}^2$ 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 Information.

Thermal, mechanical and electrical safety.

The ultrasound scanner system bk2300 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 9, 2008"

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body.

Summary of Technological Characteristics – Predicate Device Compared to Modified Device

Devices and Predicates	Predicate device K143298, Ultrasound scanner bk2300	Reference device K132346, Ultrasound scanner ProFocus 2202	Modified device (this application), Ultrasound scanner bk2300
Modes of operation Ref.: [1] Appendix G	B	B	B
	THI	THI	THI
	M,	M,	M,
	PWD,	PWD,	PWD,
	CFM ¹⁾	CFM ¹⁾	CFM ¹⁾
	and combinations	and combinations	and combinations
	CHI	CHI	CHI
	CWD,	CWD,	CWD,
	VFI	VFI	VFI
	Elastography		Elastography
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:
Indications For Use:	Fetal (incl Obstetrics)	Fetal (incl Obstetrics)	Fetal (incl Obstetrics)
	Abdominal	Abdominal	Abdominal
	Intraoperative	Intraoperative	Intraoperative
	Neurosurgery	Neurosurgery	Neurosurgery
	Pediatrics	Pediatrics	Pediatrics
	Small Parts (organs)	Small Parts (organs)	Small Parts (organs)
	Adult Cephalic	Adult Cephalic	Adult Cephalic
	Neonatal Cephalic	Neonatal Cephalic	Neonatal Cephalic
	Transrectal	Transrectal	Transrectal
	Transvaginal	Transvaginal	Transvaginal
	Transurethral	Transurethral	Transurethral
	Muskulo-skeletal (conventional and superficial)	Muskulo-skeletal (conventional and superficial)	Muskulo-skeletal (conventional and superficial)
	Cardiac	Cardiac	Cardiac
Peripheral Vessel	Peripheral Vessel	Peripheral Vessel	
Features		ECG (not monitoring)	
Features		Wi-Fi	Wi-Fi

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

A brief discussion of non-clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

The device has been evaluated for acoustic output, thermal, electrical, electromagnetic and mechanical safety, biocompatibility and has been found to conform with applicable medical device safety standards.

The system complies with the following voluntary standards:

- AIUM/NEMA UD-2, Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-3, Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 60601-1, Medical Electrical Equipment, Part 1: General requirements for safety
- IEC 60601-1-2, General requirements for safety, Collateral Standard, Electromagnetic Compatibility – Requirements and tests
- IEC 60601-2-37, Particular requirements for the safety of ultrasonic diagnostic medical and monitoring equipment
- ISO 14971, Application of Risk Management of Medical Devices
- EN ISO 10993-1, Biocompatibility
- IEC 62304, Medical Device Software – Software lifecycle processes
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

Thermal, electrical, electromagnetic, mechanical and biocompatibility safety is unchanged.

Technological characteristics compared to the predicate device

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

Minor differences consist with respect to the Ultrasound Scanner System: Optional RF wireless function.