BK Medical ApS
℅ Ms. Susana Mogensen
Regulatory Affairs Manager
Mileparken 34
Herlev 2730
DENMARK

August 1st, 2018

Re: K180737
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: June 20, 2018
Received: June 25, 2018

Dear Ms. Mogensen:

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.

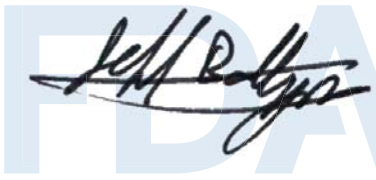
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180737

Device Name
Ultrasound Scanner System 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, Intra-operative, Intra-operative Neuro (also known as Neurosurgery), Laparoscopic, Small Organ (also known as Small Parts), Adult Cephalic (cephalic is also known as Adult Trans-cranial), Neonatal Cephalic, Trans-rectal, Trans-vaginal, Musculo-skeletal (Conventional and Superficial), Cardiac Adult, Trans-esophageal (Cardiac) 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 3)
Abdominal	P	P	P	P	P	P	P	P		P	P 3)
Intra-operative (Specify) 6)	P	P	P		P	P	P	P		P	P 3)
Intra-operative (Neuro)	P	P	P		P	P	P	P		P	P 3)
Laparoscopic	P	P	P		P	P	P	P		P	P 3)
Pediatric	P	P	P		P	P	P	P		P	P 3)
Small Organ (Specify) 7)	P	P	P		P	P	P	P		P	P 3)
Neonatal Cephalic	P	P	P		P		P	P		P	P 3)
Adult Cephalic	P	P	P	P	P		P	P		P	P 3)
Trans-rectal	P	P	P		P	P	P	P		P	P 3)
Trans-vaginal	P	P	P		P	P	P	P		P	P 3)
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											
Cardiac Adult	P	P	P	P	P		P	P		P	
Cardiac Pediatric											
Trans-esoph. (Cardiac)	P	P	P		P	P	P	P		P	
Peripheral vessel	P	P	P		P	P	P	P		P	P 2), 3)
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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)
3) Elastography
4) Continuous Wave Doppler (CWD/CW)
5) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)
6) Intra-operative: carotids, central blood vessels, aorta, vena cava, liver, biliary, pancreas, spleen, gallbladder, kidney, stomach
7) Small organ: testicles, thyroid, breast, penis, parathyroid, salivary glands, lymph nodes, superficial anatomy

(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											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel	P	P	P		P		P	P		P	P 2)
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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

(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: 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) 3)	P	P	P				P	P		P	P 2)
Intra-operative (Neuro)											
Laparoscopic											
Pediatric											
Small Organ (Specify) 4)	P	P	P				P	P		P	P 2)
Neonatal Cephalic)											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculoskeletal. (Conventional)	P	P	P				P	P		P	P 2)
Musculoskeletal. (Superficial)	P	P	P				P	P		P	P 2)
Intra-luminal											
Cardiac Adult)											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel	P	P	P				P	P		P	P 2)
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; E= added under Appendix E

Additional Comments:

1) Mode combinations:
B+M, B+D, B+C, B+D+C. (B, D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)
2) Elastography
3) Intra-operative: carotids, central blood vessels, aorta, vena cava
4) Small Organ: testicles

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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: 9011 (13L4w)

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	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										
Cardiac Adult										
Cardiac Pediatric										
Trans-esoph. (Cardiac)										
Peripheral vessel	P	P	P		P	P	P		P	P 3)
Other (Specify)										

N= new indication; P= previously cleared by FDA in K161960; 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

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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: 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											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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
3) Intra-operative: Liver, Biliary, Pancreas, Spleen, Gallbladder, Kidney, Stomach, Breast
4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

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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: 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											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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
3) Inter-operative: Liver, Biliary, Pancreas, Kidney
4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

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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: 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	Contrast Harmonic Imaging 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	P 2)
Trans-vaginal	P	P	P		P	P	P	P		P	P 2)
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculoskeletal. (Conventional)											
Musculoskeletal. (Superficial)											
Intra-luminal											
Cardiac Adult)											
Cardiac Pediatric)											
Trans-esoph. (Cardiac)											
Peripheral vessel)											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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
3) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)

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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: 9019 (E10C4)

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	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.)										
Musculoskeletal. (Conventional)										
Musculoskeletal. (Superficial)										
Intra-luminal										
Cardiac Adult										
Cardiac Pediatric										
Trans-esoph. (Cardiac)										
Peripheral vessel										
Other (Specify)										

N= new indication; P= previously cleared by FDA in K161960; 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

(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: 9022 (10L2w)

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	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										
Cardiac Adult										
Cardiac Pediatric										
Trans-esoph. (Cardiac)										
Peripheral vessel	P	P	P		P	P	P		P	P 2),3)
Other (Specify)										

N= new indication; P= previously cleared by FDA in K161960; 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
3) Vector Flow Imaging (VFI)

(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	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	P	P	P		P	P	P	P		P	P 2)
Abdominal	P	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	P 2)
Small Organ (Specify)											
Neonatal Cephalic)											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculoskeletal. (Conventional)											
Musculoskeletal. (Superficial)											
Intra-luminal											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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
3) 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)

Diagnostic Ultrasound Indications for Use Form

System: BK2300

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.)											
Musculoskeletal. (Conventional)	P	P	P		P	P	P	P		P	P 3)
Musculoskeletal. (Superficial)											
Intra-luminal											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel	P	P	P		P	P	P	P		P	P 3)
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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
4) 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)

Diagnostic Ultrasound Indications for Use Form

System: BK2300

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											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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
4) 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)

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											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. Cardiac	P	P	P	P	P	P	P	P		P	
Peripheral vessel)											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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)
3) 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)

bk ultrasound
powered by analogic

Diagnostic Ultrasound Indications for Use Form

System: BK2300

Transducer: 9029 (E13C2)

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	E	E	E		E	E	E	E		E	E 2)
Trans-vaginal	E	E	E		E	E	E	E		E	E 2)
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skel. (Conventional)											
Musculo-skel. (Superficial)											
Intra-luminal											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. Cardiac											
Peripheral vessel)											
Other (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E (LTF: 10.13.2016)

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
3) 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)

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.)											
Musculoskeletal (Conventional)	P	P	P		P	P	P	P		P	P 3)
Musculoskeletal. (Superficial)	P	P	P		P	P	P	P		P	P 3)
Intra-luminal											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel	P	P	P		P	P	P	P		P	P 3), 5)
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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
4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)
5) Vector Flow Imaging (VFI)

(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: 9038 (X14L4)

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 2)	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	E	E	E		E	E	E	E		E	E 3)
Trans-vaginal	E	E	E		E	E	E	E		E	E 3)
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculoskeletal. (Conventional)											
Musculoskeletal. (Superficial)											
Intra-luminal											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel											
Other (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E (LTF 10.09.2017)

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)
3) Elastography

(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: 9040 (6C2)

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	P 2)
Abdominal	P	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.)											
Musculoskeletal. (Conventional)	P	P	P		P	P	P	P		P	P 2)
Musculoskeletal. (Superficial)											
Intra-luminal											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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)

(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: 9048 (E14CL4b)

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	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), 3)
Trans-vaginal	P	P	P		P	P	P		P	P 2), 3)
Trans-urethral										
Trans-esoph. (non-Card.)										
Musculo-skel. (Conventional)										
Musculo-skel. (Superficial)										
Intra-luminal										
Cardiac Adult										
Cardiac Pediatric										
Trans-esoph. (Cardiac)										
Peripheral vessel)										
Other (Specify)										

N= new indication; P= previously cleared by FDA in K161960; 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
3) 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)

Diagnostic Ultrasound Indications for Use Form

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	P 3)
Small Organ (Specify) 4)	P	P	P		P		P	P		P	P 3)
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculoskeletal. (Conventional)	P	P	P		P		P	P		P	P 3)
Musculoskeletal. (Superficial)	P	P	P		P		P	P		P	P 3)
Intra-luminal											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel	P	P	P		P		P	P		P	P 2) 3)
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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)
3) Elastography
4) Small Organ: breast, thyroid, testes

(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: 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											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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

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) 3)	P	P	P		P		P	P		P	P 2)
Intra-operative (Neuro)	P	P	P		P		P	P		P	P 2)
Laparoscopic											
Pediatric	P	P	P		P		P	P		P	P 2)
Small Organ (Specify)											
Neonatal Cephalic	P	P	P		P		P	P		P	P 2)
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculoskeletal. (Conventional)											
Musculoskeletal. (Superficial)											
Intra-luminal											
Cardiac Adult)											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel)											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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
3) Intra-operative: gallbladder

(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: 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	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-operative Specify 2)	P	P	P		P	P	P		P	
Intra-operative (Neuro)	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.)										
Musculoskeletal. (Conventional)										
Musculoskeletal. (Superficial)										
Intra-luminal										
Cardiac Adult										
Cardiac Pediatric										
Trans-esoph. (Cardiac)										
Peripheral vessel										
Other (Specify)										

N= new indication; P= previously cleared by FDA in K161960; 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

(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: 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 4)
Intra-operative (Neuro)											
Laparoscopic	E	E	E		E		E	E		E	P 4)
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculoskeletal. (Conventional)											
Musculoskeletal. (Superficial)											
Intra-luminal											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel)											
Other (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E (LTF: 05.24.2017)

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: Laparoscopic procedure for abdominal region, Liver, Biliary, Pancreas, Kidney, Stomach, Uterus
3) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)
4) Elastography

(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: 9067 (E14C4)

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	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 2)
Trans-vaginal	P	P	P		P	P	P		P	P 2)
Trans-urethral										
Trans-esoph. (non-Card.)										
Musculoskeletal. (Conventional)										
Musculoskeletal. (Superficial)										
Intra-luminal										
Cardiac Adult										
Cardiac Pediatric										
Trans-esoph. (Cardiac)										
Peripheral vessel)										
Other (Specify)										

N= new indication; P= previously cleared by FDA in K161960; 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

(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: 9070 (18L5)

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	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative (Neuro)										
Laparoscopic										
Pediatric										
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.)										
Musculoskeletal. (Conventional)	P	P	P		P	P	P		P	P 3)
Musculoskeletal. (Superficial)	P	P	P		P	P	P		P	P 3)
Intra-luminal										
Cardiac Adult										
Cardiac Pediatric										
Trans-esoph. (Cardiac)										
Peripheral vessel)	P	P	P		P	P	P		P	P 3)
Other (Specify)										

N= new indication; P= previously cleared by FDA in K161960; 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

(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: BK23000

Transducer: 9076 (I13C3f)

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)	N	N	N		N	N	N	N		N	N 4)
Intra-operative (Neuro)											
Laparoscopic	N	N	N		N	N	N	N		N	N 4)
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											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel											
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) Intra-operative: Liver, Biliary, Pancreas, Kidney, Stomach, Uterus
3) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI)
4) Elastography

(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											
Cardiac Adult 3)	P	P	P	P	P		P	P		P	
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel											
Other (Specify)											

N= new indication; P= previously cleared by FDA in K161960; 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)
3) Adult Cardiac: Not for direct use on the heart

(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: 9081 (18L5s)

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	E	E	E		E	E	E	E		E	E 3)
Small Organ (Specify 2)	E	E	E		E	E	E	E		E	E 3)
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skel. (Conventional)	E	E	E		E	E	E	E		E	E 3)
Musculo-skel. (Superficial)	E	E	E		E	E	E	E		E	E 3)
Intra-luminal											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel	E	E	E		E	E	E	E		E	E 3)
Other (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E (LTF:10.10.2016)

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

(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: 9085 (5Cle)

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	E	E	E		E	E	E	E		E	E 2)
Abdominal	E	E	E		E	E	E	E		E	E 2)
Intra-operative (Specify)											
Intra-operative (Neuro)											
Laparoscopic											
Pediatric											
Small Organ (Specify 2)											
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)											
Musculo-skel. (Conventional)	E	E	E		E	E	E	E		E	E 2)
Musculo-skel. (Superficial)											
Intra-luminal											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											
Peripheral vessel											
Other (Specify)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E (LTF:10.13.2016)

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

(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)

5. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. Submitter:

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Date Prepared: July 24, 2018

II. Device Names / Common Names / Classification Names:

Trade Name:	Ultrasound Scanner System bk2300
Common Name:	Ultrasound Scanner System
Classification Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN, IYO, ITX
Class:	II
Regulation Number:	21 CFR §892.1550, §892.1560, §892.1570
Classification Panel:	Radiology

III. Identification of Predicate or Legally Marketed Devices:

Ultrasound Scanner System bk2300 – K161960 (10/17/2016)

IV. Device Description:

The Ultrasound Scanner System bk2300 is a multi-purpose mobile, software controlled diagnostic Ultrasound Scanner 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:

- Linear Array
- Phased Linear Array
- Convex / Curved Array

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

- Surface Contact,
- Intra-operative,
- Laparoscopic, or
- Endocavity

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.

V. Indications / Intended 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, Intra-operative, Intra-operative Neuro (also known as Neurosurgery), Laparoscopic, Small Organ (also known as Small Parts), Adult Cephalic (cephalic is also known as Adult Trans-cranial), Neonatal Cephalic, Trans-rectal, Trans-vaginal, Musculo-skeletal (Conventional and Superficial), Cardiac Adult, Trans-esophageal (Cardiac) and Peripheral Vessel (also known as Peripheral Vascular).

Contraindications:

The Ultrasound Scanner System bk2300 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.

VI. Comparison of Technological Characteristics with the Predicate Device:

Item	**Ultrasound Scanner System bk2300** (predicate device)	**Ultrasound Scanner System bk2300** (proposed device)
Modes of operation	B, M, PWD, CFM* and combinations, Tissue Harmonic Imaging, Vector Flow Analysis, Continuous Wave Doppler (CWD), Elastography, Contrast Imaging	B, M, PWD, CFM* and combinations, Tissue Harmonic Imaging, Vector Flow Analysis, Continuous Wave Doppler (CWD), Elastography, Contrast Imaging

Item	**Ultrasound Scanner System bk2300** (predicate device)	**Ultrasound Scanner System bk2300** (proposed device)
Intended 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 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.
Clinical Applications	Fetal (including Obstetrics), Abdominal, Pediatric, Intra-operative, Intra-operative Neuro (also known as Neurosurgery), Laparoscopic, Small Organ (also known as Small Parts), Adult Cephalic (cephalic is also known as Adult Trans-cranial), Neonatal Cephalic, Trans-rectal, Trans-vaginal, Musculo-skeletal (Conventional and Superficial), Cardiac Adult, Trans-esophageal (Cardiac) and Peripheral Vessel (also known as Peripheral Vascular).	Fetal (including Obstetrics), Abdominal, Pediatric, Intra-operative, Intra-operative Neuro (also known as Neurosurgery), Laparoscopic, Small Organ (also known as Small Parts), Adult Cephalic (cephalic is also known as Adult Trans-cranial), Neonatal Cephalic, Trans-rectal, Trans-vaginal, Musculo-skeletal (Conventional and Superficial), Cardiac Adult, Trans-esophageal (Cardiac) and Peripheral Vessel (also known as Peripheral Vascular).
Transducers	9002, 9009, 9011, 9015, 9016, 9018, 9019, 9022, 9023, 9024, 9026, 9029, 9032, 9038, 9040, 9048, 9051, 9052, 9062, 9063, 9066, 9067, 9070, 9077, 9081, 9085	9002, 9009, 9011, 9015, 9016, 9018, 9019, 9022, 9023, 9024, 9026, 9029, 9032, 9038, 9040, 9048, 9051, 9052, 9062, 9063, 9066, 9067, 9070, 9077, 9081, 9085 New transducers: 9076
Features	ECG (not monitoring)	ECG (not monitoring)
Features	Wi-Fi	Wi-Fi
Special Features		Laser pointer for guidance of needles: Class 2 Laser product.

*CFM = Color Flow Mapping = Color Doppler and Amplitude (Power) Doppler

VII. Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

Non-clinical /Performance - Bench Testing:

Bench testing was performed and the Ultrasound Scanner System bk2300 fulfilled the requirements of the following FDA consensus standards and requirements set forth in FDA guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Scanner System s and Transducers" issued on September 9, 2008 as it pertains to Track 3 devices:

IEC 60601-2-37 - Medical Electrical Equipment - Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment

IEC 62359 - Ultrasonics - Field Characterization - Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields

NEMA UD 2 - Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

IEC 62366-1 - Medical Devices - Part 1: Application of Usability Engineering to Medical Devices

IEC 60825-1 - safety of laser products - part 1: equipment classification, and requirements [including: technical corrigendum 1 (2008), interpretation sheet 2 (2007)].

Testing to the above-mentioned standards was performed on the proposed Ultrasound Scanner System bk2300. The results of these tests demonstrate that the proposed device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

Biocompatibility:

The main Ultrasound Scanner System bk2300 console is not patient contacting. However, the transducers are patient contacting and categorized per Section 5.2 and Table A1 of AAMI/ANSI/ISO 10993-1 according to their clinical use. The transducers comply with the applicable biocompatibility standard requirements.

Sterilization:

The Ultrasound Scanner System bk2300 is not sold as a sterile device. The transducers require reprocessing prior to use. Testing to support recommended methods for reprocessing was performed in accordance with TIR-12 and TIR-30.

Electrical Safety & Electromagnetic Compatibility (EMC):

Electrical safety testing is compliant with the following standards:

- AAMI/ANSI/ES 60601-1: 2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/ (R) 2012 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Edition 3: 2007-03 - medical electrical equipment - part 1-2: general requirements for basic safety and essential performance

Laser Verification and Validation Testing:

Safety of laser products testing is compliant with the following standards:

- IEC 60825-1 Edition 2.0 2007-03, safety of laser products - part 1: equipment classification, and requirements [including: technical corrigendum 1 (2008), interpretation sheet 1 (2007), interpretation sheet 2 (2007)]

Software Verification and Validation Testing:

Software verification and validation testing were conducted and documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern. The Ultrasound Scanner System bk2300 complies with EN IEC 62304, Medical Device Software Life-Cycle Processes. The submission contains performance data which demonstrates conformance to special controls for medical devices containing software.

Animal Testing:

Not applicable – animal testing was not required to support substantial equivalence to the predicate device.

Clinical Studies:

Not applicable – clinical studies were not required to support substantial equivalence to the predicate device.

VIII. Conclusion:

The proposed Ultrasound Scanner System bk2300 is substantially equivalent to the predicate Ultrasound Scanner System bk2300 (K161960). The differences between the proposed and predicate device do not impact the safety and effectiveness of the proposed device. Performance testing supports that the proposed device is substantially equivalent to the legally marketed predicate device.