

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

October 17, 2016

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

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

Dear Ms. Provencher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

<u>http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</u> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

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

Enclosure

# Indications for Use

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

Device Name bk2300

The system is a diagnostic ultrasound imaging system used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow analysis and puncture and biopsy guidance.

The clinical applications and exam types include: Fetal (including Obstetrics), Abdominal, Pediatric, Small Organ (also known as Small Parts), Adult Cephalic (also known as Adult Trans cranial), Neonatal Cephalic, Intra-operative, Intra-operative (Neuro), Trans rectal, Trans-vaginal, Trans-urethral, Musculo-skeletal (Conventional and Superficial), Cardiac Adult, Trans-esophageal Cardiology, and Peripheral Vessel (also known as Peripheral Vascular).

Contraindications:

• The 2300 Ultrasound System is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

• The Cardiac Adult application is not intended for direct use on the heart.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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### System: bk2300

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

Clinical Application	Modes											
Specific (Tracks I & III)	В	М	PWD	CWD 4)	Tissue Harmonic Imaging	CHI 5)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other	
Ophthalmic												
Fetal	Р	Р	Р	Р	Р	Р	Р	Р		Р	P 3)	
Abdominal	Р	Р	Р	Р	Р	Р	Р	Р		Р	P 3)	
Intra-operative (Specify)	P	P	Р	Р	Р	Р	P	Р		Р	P 3)	
Intra-operative (Neuro)	P	Р	Р	Р	Р	Р	Р	Р		Р	P 3)	
Laparoscopic							A MARCH THE					
Pediatric	P	Р	Р	P	Р	Р	Р	Р		Р	P 3)	
Small Organ (Specify)	Р	P	Р	Р	P	Р	Р	P		Р	P 3)	
Neonatal Cephalic	Р	Р	Р	Р	Р	Р	P	Р		Р	P 3)	
Adult Cephalic	Р	P	Р	Р	Р	Р	Р	Р		Р	P 3)	
Trans-rectal	Р	Р	Р	Р	Р	Р	Р	Р		Р	P 3)	
Trans-vaginal	Р	P	Р	Р	Р	Р	P	Р		Р	P 3)	
Trans-urethral	Р	Р	Р	Р	Р	Р	Р	Р		Р	P 3)	
Trans-esoph. (non-Card.)	NAME OF A					Salay/2217						
Musculo-skel. (Conventional)	Р	P	Р	Р	Р	Р	Р	Р		Р	P 3)	
Musculo-skel. (Superficial)	Р	Р	Р	Р	Р	Р	Р	Р		Р	P 3)	
Intra-luminal								Salar Salar			1.5	
Cardiac Adult	Р	P	Р	Р	Р	Р	Р	Р		Р		
Cardiac Pediatric												
Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	N		N	-	
Peripheral vessel	Р	Р	Р	Р	Р	Р	Р	P		P	P 2) P 3)	
Other (Specify)												

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

Additional Comments:

1) Mode combinations:

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

2) Vector Flow Imaging (VFI): Previously cleared in K143298

3) Elastography: Previously cleared in K143298

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

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

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

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

#### 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)	В	М	PWD	CWD 2)	Tissue Harmonic Imaging	CHI 3)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other		
Ophthalmic													
Fetal									1				
Abdominal													
Intra-operative (Specify)													
Intra-operative (Neuro)													
Laparoscopic			State Production							San Cal	a vices		
Pediatric				-					-				
Small Organ (Specify)				(			1						
Neonatal Cephalic													
Adult Cephalic							an a						
Trans-rectal													
Trans-vaginal													
Trans-urethral													
Trans-esoph. (non-Card.)	No. Lossie	(And		Part and the second		J.Y. Bart	Ser-Sty	Constant States of		EVER CONSUL	1		
Musculo-skel. (Conventional)			No.										
Musculo-skel. (Superficial)			(			8							
Intra-luminal 17)	and the second second	No. Standard	and the second	REAL PROPERTY	A Stand of the second		Carl Carlo -	100		1-5-5-5-5	10100		
Other (Specify)													
Cardiac Adult								·					
Cardiac Pediatric													
Trans-esoph. Cardiac	N	N	N	N	N	N	N	N		N			
Other (Specify)									_				
Peripheral vessel)				and the second second									
Other (Specify)								er ale transiere de					
Other (Specify)		_		-									
Other (Specify)													

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

Additional Comments:

1) Mode combinations:

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

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

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

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

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

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)	В	M	PWD	CWD	Tissue Harmonic Imaging	CHI	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Othe
Ophthalmic										Part and the state of	
Fetal	P	P	Р		Р		P	Р		Р	P 2)
Abdominal	P	Р	P	1	Р		Р	Р		Р	P 2)
Intra-operative (Specify)				-							
Intra-operative (Neuro)						e 1808 - 520					
Laparoscopic							1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1				
Pediatric	P	P	Р		Р		Р	Р		Р	P 2)
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal											
Trans-vaginal							-				
Trans-urethral											
Trans-esoph. (non-Card.)	T								A LAR AND AND	In the set of the set of the	- Reder
Musculo-skel. (Conventional)	Р	Р	Р		Р		Р	Р		Р	P 2)
Musculo-skel. (Superficial)											
Intra-luminal	0214 457.859		CERCERCITE OF	a subscription of the			No. State of State				
Other (Specify)				0.			1				
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)											01035
Other (Specify)											
Peripheral vessel	Р	Р	P	1000-01-000	Р	100/	P	Р		Р	P 2)

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

Additional Comments:

1) Mode combinations:

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

2) Elastography: Previously cleared in K143298

(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)

System: bk2300

Transducer: 9009 (X18L5s)

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

Clinical Application	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	14.1.19.2	State Ster	SE ENGLADER		Modes					
Specific (Tracks I & III)	В	M	PWD	CWD	Tissue Harmonic Imaging	CHI	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic									0_0		<u> </u>
Fetal			30								
Abdominal									- 1.62		<u> </u>
Intra-operative (Specify)	Р	Р	Р		P		Р	Р		Р	
Intra-operative (Neuro)											
Laparoscopic			Contraction of the	100 M							No Compt
Pediatric									-		1
Small Organ (Specify)	Р	Р	Р		Р		Р	Р	10 - 10 Are	р	
Neonatal Cephalic)											
Adult Cephalic									29 - 102 - S	5-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1	
Trans-rectal								instance in	(197) - 197	1	
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)	0000 6-00404	2.00	CERTENCES I		Survey and						
Musculo-skel. (Conventional)	P	Р	Р		Р		Р	Р		Р	
Musculo-skel. (Superficial)	P	Р	Р		P		Р	Р		P	1.00
Intra-luminal		11-22-55			Contraction of the			State State State			
Other (Specify)						and a second					
Cardiac Adult)											
Cardiac Pediatric											
Trans-esoph. (Cardiac)	60 Press (1	1.000	State State	and the second	And the second second second	12-11/27	1000				
Other (Specify)						11					
Peripheral vessel	Р	Р	Р		Р		р	Р		Р	

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

Additional Comments:

1) Mode combinations:

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

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

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

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

System: bk 2300

CIL

Transducer: 9011 (13L4w)

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

Clinical Application									
Specific (Tracks I & III)	В	M	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal									1
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic		2012					A		and and a la
Pediatric	Р	P	Р	Р	Р	Р		Р	P 3)
Small Organ (Specify) 2)	P	Р	Р	Р	Р	Р		P	P 3)
Neonatal Cephalic								· · · ·	1 5)
Adult Cephalic									
Trans-rectal									
Trans-vaginal				0					
Trans-urethral									
Trans-esoph. (non-Card.)					States and			STORES DATE:	
Musculo-skel. (Conventional)	Р	Р	Р	Р	Р	Р		Р	P 3)
Musculo-skel. (Superficial)	Р	Р	Р	Р	Р	Р		P	P 3)
Intra-luminal								Constanting of the	
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Trans-esoph. (Cardiac)		Select			and the second			Street and	
Other (Specify)									
Peripheral vessel	P	Р	Р	Р	Р	Р		Р	P 3)
Other (Specify)									)

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

Additional Comments:

1) Mode combinations:

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

2) Small Organ: thyroid, breast, testes, penis, parathyroid, salivary glands, lymph nodes.

3) Elastography: Previously cleared in K143298

(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)

System: bk2300 (bk5000)

Transducer: 9015 (I14C5I)

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

Clinical Application						Modes	Section Section			Contraction of the second	
Specific (Tracks I & III)	В	M	PWD	CWD	Tissue Harmonic Imaging	CHI 4)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic									0_0		1
Fetal											
Abdominal											
Intra-operative (Specify) 3)	Р	Р	Р		P	Р	Р	Р		Р	P 2)
Intra-operative (Neuro)										1	
Laparoscopic					Description of the		14 1 1 10 10 10 10 10 10 10 10 10 10 10 10	Segretaria (	Press and Party	No. S. A.S. & MARK	Carlo and
Pediatric	Р	P	Р		Р	Р	Р	Р		р	P 2)
Small Organ (Specify)				541AD - 23.5 TASE		C. Indiana					
Neonatal Cephalic)				- s - Konrosh							
Adult Cephalic					- 24 - 19 - 19 - 19 - 19 - 19 - 19 - 19 - 1						
Trans-rectal											
Trans-vaginal											
Trans-urethral				1.85							
Trans-esoph. (non-Card.)		1000									-
Musculo-skel. (Conventional)											-
Musculo-skel. (Superficial)											
Intra-luminal	new Mareley		3332302								
Other (Specify)											
Cardiac Adult									NAC STATE		
Cardiac Pediatric											
Trans-esoph. (Cardiac)	Sec. Stand			- 10			Contraction of the second	C. S. S. S. S. S. S.	A Martine Part		
Other (Specify)											
Peripheral vessel											

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

Additional Comments:

1) Mode combinations:

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

- 2) Elastography: Previously cleared in K143298
- 3) Inter-operative: Liver, Biliary, Pancreas, Kidney, Stomach, Breast
- 4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

(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)

System: bk2300 (bk5000)

### Transducer: 9016 (I14C5T)

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

Clinical Application	194	Modes											
Specific (Tracks I & III)	В	M	PWD	CWD	Tissue Harmonic Imaging	CHI 4)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other		
Ophthalmic				n									
Fetal													
Abdominal	P	P	Р		Р	Р	Р	Р		Р	P 2)		
Intra-operative (Specify) 3)	Р	Р	P	0 	Р	Р	Р	Р		Р	P 2)		
Intra-operative (Neuro)				6 0	1.516								
Laparoscopic	ANT PROPER	12.00	(Station of the		A DESCRIPTION OF	10000000	15-6-11-225	DE RESERVAND			CHOT 22		
Pediatric						Lange and							
Small Organ (Specify)				1907							1		
Neonatal Cephalic							and an and a second						
Adult Cephalic										and the second second	and an out of the second		
Trans-rectal		lunes		The second s			Same and the second						
Trans-vaginal							and a second respect to a						
Trans-urethral					and the state of the state								
Trans-esoph. (non-Card.)	14- 1 5 - 1 2 K					No. State							
Musculo-skel. (Conventional)													
Musculo-skel. (Superficial)													
Intra-luminal				Provide Statistics		La Sin U				<b>Hasanaka</b> Salah	Build Ba		
Other (Specify)													
Cardiac Adult													
Cardiac Pediatric													
Trans-esoph. (Cardiac)							S. California	A Contraction of the	A BOUNDER	The state of the second	1.S.R. U.V.		
Other (Specify)													
Peripheral vessel													

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

Additional Comments:

1) Mode combinations:

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

- 2) Elastography: Previously cleared in K143298
- 3) Inter-operative: Liver, Biliary, Pancreas, Kidney
- 4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

(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)

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

System: bk2300 (bk3000, bk5000)

Transducer: 9018 (E14C4t)

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

Clinical Application						Modes					
Specific (Tracks I & III)	В	М	PWD	CWD	Tissue Harmonic Imaging	CHI 3)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic									<u> </u>		1
Fetal											1
Abdominal											
Intra-operative (Specify)									COLOR D		110000
Intra-operative (Neuro)							-			the state of a	1
Laparoscopic		1275		1 - A Contra							
Pediatric			(								
Small Organ (Specify)									500 M 1990		
Neonatal Cephalic)									10000		
Adult Cephalic)											-
Trans-rectal	P	P	Р		Р	Р	Р	Р		Р	P2)
Trans-vaginal	P	Р	Р		Р	Р	P	Р	711125	Р	P2)
Trans-urethral									N		/
Trans-esoph. (non-Card.)	and showing		Les and the second				10000000000				
Musculo-skel. (Conventional)							1	- How And Address			
Musculo-skel. (Superficial)											
Intra-luminal								and the second			1091.00
Other (Specify)											
Cardiac Adult)											
Cardiac Pediatric)											
Trans-esoph. (Cardiac)	(V/S) = 5 (2)						19.				1200
Other (Specify)											
Peripheral vessel)											
Other (Specify)	1										

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

Additional Comments:

1) Mode combinations:

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

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

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

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

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

System: bk2300

Transducer: 9019 (E10C4)

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

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

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

Additional Comments:

1) Mode combinations:

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

2) Elastography: Previously cleared in K143298

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

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

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

System: bk2300

Transducer: 9022 (10L2w)

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

Clinical Application									
Specific (Tracks I & III)	В	М	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic						1			
Fetal				and the second					
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic				St. Asternet St.					
Pediatric									
Small Organ (Specify)									
Neonatal Cephalic									
Adult Cephalic					e e e e e e e e e e e e e e e e e e e				
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skel. (Conventional)									
Musculo-skel. (Superficial)									
Intra-luminal		122/201							
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric							1		
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel	P	Р	Р	Р	Р	Р		Р	P 2), P 3)
Other (Specify)									

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

Additional Comments:

1) Mode combinations:

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

2) Elastography: Previously cleared in K143298

3) Vector Flow Imaging (VFI): Previously cleared in K143298

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

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

### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

### System: bk2300 Transducer: 9023 (6C2s)

Г

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

Clinical Application									
Specific (Tracks I & III)	В	М	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal	P	Р	Р	Р	Р	Р		Р	P 2), P 3)
Abdominal	P	Р	Р	Р	Р	Р		Р	P 2), P 3)
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	Р	Р	Р	Р	Р	Р		Р	P 2), P 3)
Small Organ (Specify)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal				A A A A A A A A A A A A A A A A A A A					
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skel. (Conventional)									
Musculo-skel. (Superficial)									Ghangli ann an th
Intra-luminal								121.00	
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)								- 100	
Peripheral vessel									
Other (Specify)									

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

Additional Comments:

1) Mode combinations:

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

2) Elastography: Previously cleared in K143298

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

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

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR) Prescription Use (Per 21 CFR 801.109)

System: bk2300 (bk3500, bk5000)

Transducer: 9024 (I12C5b)

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

Clinical Application						Modes					-
Specific (Tracks I & III)	В	М	PWD	CWD	Tissue Harmonic Imaging	CHI 4)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic				2.5.5.7							
Fetal			101000								
Abdominal											
Intra-operative (Specify 2)	P	Р	Р		Р	Р	Р	Р		Р	P 3)
Intra-operative (Neuro)											1000 C
Laparoscopic											
Pediatric					4.5						
Small Organ (Specify)							lane o marent				
Neonatal Cephalic)											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)		in the second			NO SHORE		A State of the second			ALCONTRACTORS	
Musculo-skel. (Conventional)	Р	Р	Р		Р	Р	Р	Р		Р	P 3)
Musculo-skel. (Superficial)											
Intra-luminal					Section 10	Bes VELOVA	and the second		West Carlos	and the second second	1-172.00
Other (Specify)									X III		
Cardiac Adult											
Cardiac Pediatric									CONSULTA -		
Trans-esoph. (Cardiac)								Carlos and an			
Other (Specify)											
Peripheral vessel	Р	Р	Р		Р	Р	Р	Р		Р	P 3)

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

Additional Comments:

1) Mode combinations:

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

- 2) Intra-operative: Liver, Biliary, Pancreas, Kidney
- 3) Elastography: Previously cleared in K143298
- 4) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298

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

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

System: bk2300 (bk5000)

Transducer: 9026 (X12C4)

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

Clinical Application	Contraction of the second				1	Modes					
Specific (Tracks I & III)	В	M	PWD	CWD	Tissue Harmonic Imaging	CHI 4)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic					1		1				
Fetal											
Abdominal											
Intra-operative (Specify 2)	Р	Р	Р		Р	Р	Р	Р		Р	P 3)
Intra-operative (Neuro)											1
Laparoscopic	1.200 M.C. 19	5.25	March 18				The second second second	C.Z. States Mine			1269
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic											
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1										
Musculo-skel. (Conventional)											
Musculo-skel. (Superficial)									19 11 16 - 5		
Intra-luminal	7.28 3 2.23 M			NS ON LINE OF					Contraction of the second	State State States	
Other (Specify)											
Cardiac Adult	a services										
Cardiac Pediatric											
Trans-esoph. (Cardiac)						(Carton and					
Other (Specify)	-										
Peripheral vessel											

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

Additional Comments:

1) Mode combinations:

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

- 2) Intra-operative: Pancreas, Kidney, Liver
- 3) Elastography: Previously cleared in K143298

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

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

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

System: bk2300

Transducer: 9032 (8L2)

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

Clinical Application	ASSA DOWN			N.		Modes	A STATE OF AN			Station and the second	
Specific (Tracks I & III)	В	М	PWD	CWD	Tissue Harmonic Imaging	CHI 4)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic				and 10196					00		+
Fetal											1
Abdominal											
Intra-operative (Specify)											
Intra-operative (Neuro)											t
Laparoscopic	SPAN BRITS	1110350			St. Charles				and the second second		
Pediatric	P	Р	Р		Р	Р	Р	р		P	P 3)
Small Organ (Specify 2)	P	P	Р		Р	Р	Р	Р		P	P 3)
Neonatal Cephalic											1.5)
Adult Cephalic											
Trans-rectal											-
Trans-vaginal						·····	-				
Trans-urethral											
Trans-esoph. (non-Card.)								La la Carte Carta	10.00	Contraction of the local distance of the loc	No. of Contraction
Musculo-skel. (Conventional)	Р	Р	Р		Р	Р	Р	Р		Р	P 3)
Musculo-skel. (Superficial)	Р	Р	P		Р	Р	P	P		P	P 3)
Intra-luminal	CAR DO AND	N.S. SAN	RUNDER I			Colling Sector	No. Constant		Call Internet	The second second	1.5)
Other (Specify)											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)	Sales Plating										A CONTRACTOR
Other (Specify)											
Peripheral vessel	Р	Р	Р		Р	Р	р	Р		р	P 3)

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

Additional Comments:

1) Mode combinations:

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

- 2) Small Organ: Thyroid, Breast, Testes
- 3) Elastography: Previously cleared in K143298

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

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

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

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

System: bk2300

Transducer: 9040 (6C2)

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

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

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

Additional Comments:

1) Mode combinations:

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

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

(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)

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

System: bk 2300 (bk3000, bk5000)

Transducer: 9048 (E14CL4b)

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

Clinical Application									
Specific (Tracks I & III)	В	М	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)				1					
Intra-operative (Neuro)									
Laparoscopic					100 M 100 M		And the Parts		We we also
Pediatric								and the second	
Small Organ (Specify)									
Neonatal Cephalic								1	
Adult Cephalic					- 54111 111				
Trans-rectal	P	P	Р	Р	Р	Р		Р	P 2), P 3)
Trans-vaginal	P	Р	Р	Р	Р	Р		Р	P 2), P 3)
Trans-urethral									
Trans-esoph. (non-Card.)							in a second		
Musculo-skel. (Conventional)								MARCE IN CONTRACTOR	
Musculo-skel. (Superficial)									
Intra-luminal			She was in				Sale Presses		
Other (Specify)									
Cardiac Adult									
Cardiac Pediatric									
Trans-esoph. (Cardiac)								ARE STATED	
Other (Specify)									
Peripheral vessel)									
Other (Specify)									

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

Additional Comments:

1) Mode combinations:

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

2) Elastography: Previously cleared in K143298

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

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

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

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

System: bk2300

Transducer: 9051 (14L3)

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

Clinical Application	1000	1 States				Modes					
Specific (Tracks I & III)	В	M	PWD	CWD	Tissue Harmonic Imaging	Contrast Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic					1						
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative (Neuro)											
Laparoscopic			S Man Prices		Provide States			800000000			
Pediatric	P	Р	Р		Р		P	Р		Р	P3)
Small Organ (Specify 2)	P	Р	Р	n south and a second	Р		Р	Р		Р	P3)
Neonatal Cephalic											
Adult Cephalic										7	
Trans-rectal											
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)		S			No. State State						NO TEST
Musculo-skel. (Conventional)	P	Р	Р		Р		Р	Р		Р	P3)
Musculo-skel. (Superficial)	P	P	Р		Р		Р	Р		Р	P3)
Intra-luminal							Real Street Street	elevel second		State of the second	13.200
Other (Specify)											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac )			Sidon all sido	AV. 5 01.25			Louis and				
Other (Specify)						- 200 - 200 					
Peripheral vessel	Р	Р	Р		Р		Р	Р		Р	P3) P4)
Other (Specify )								0			

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

Additional Comments:

1) Mode combinations:

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

- 2) Small Organ: Breast, Thyroids, Testes
- 3) Elastography: Previously cleared in K143298
- 4) Vector Flow Imaging (VFI): Previously cleared in K143298

(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)

System: bk2300 (bk3000, bk5000)

Transducer: 9052 (20R3)

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

Clinical Application			and the second			Modes					
Specific (Tracks I & III)	В	M	PWD	CWD	Tissue Harmonic Imaging	CHI	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal											
Abdominal				All Control of Control		A 140 - A 2					<u> </u>
Intra-operative (Specify)											
Intra-operative (Neuro)											
Laparoscopic		12.00		Ine Care States			No. 1 No. 1				North Contract
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic)											
Adult Cephalic											
Trans-rectal	P										
Trans-vaginal	Р						1				
Trans-urethral											
Trans-esoph. (non-Card.)				S. Martin Strange						TO CONTRACTOR AND	
Musculo-skel. (Conventional)											
Musculo-skel. (Superficial)											
Intra-luminal			Marshell Marshell								
Other (Specify)											
Cardiac Adult											
Cardiac Pediatric				1000							Allo Alfred etc
Trans-esoph. (Cardiac)		182133	Mary States	States and	at standards		ine water and				
Other (Specify)											1.00
Peripheral vessel											

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

Additional Comments:

1) Mode combinations:

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

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

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

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

System: bk2300

Transducer: 9062 (N13C5)

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

Clinical Application	5 1	11 - 10 - 10				Modes					12122
Specific (Tracks I & III)	В	М	PWD	CWD	Tissue Harmonic Imaging	Contrast Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal										11-	
Abdominal											1
Intra-operative (Specify 2)	Р	P	Р		Р		Р	Р		Р	P3)
Intra-operative (Neuro)	Р	Р	Р		Р		Р	Р		Р	P3)
Laparoscopic											
Pediatric	P	Р	Р		Р		Р	Р		Р	P3)
Small Organ (Specify)											
Neonatal Cephalic	Р	Р	Р		Р		Р	Р		Р	P3)
Adult Cephalic											
Trans-rectal										- 1134 - X	
Trans-vaginal											
Trans-urethral											
Trans-esoph. (non-Card.)					The local states of the						
Musculo-skel. (Conventional)						[					
Musculo-skel. (Superficial)											
Intra-luminal	MIS 175.17	1.50.51									Babanta
Other (Specify)				0							
Cardiac Adult)											
Cardiac Pediatric						1					
Trans-esoph. (Cardiac)	Carl Training		STREET, U						Station of Second		
Other (Specify)											
Peripheral vessel)										10.0	
Other (Specify)						2, 2)					

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

Additional Comments:

1) Mode combinations:

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

- 2) Inter-operative: Gallbladder
- 3) Elastography: Previously cleared in K143298

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

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

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

System: bk2300 (bk5000)

Transducer: 9063 (N11C5s)

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

Clinical Application	1.1.1			Carling and		Modes					
Specific (Tracks I & III)	В	М	PWD	CWD	Tissue Harmonic Imaging	CHI 3)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Othe
Ophthalmic											
Fetal				0							
Abdominal											
Intra-operative (Specify 2)	Р	Р	Р		P	Р	Р	Р		Р	
Intra-operative (Neuro)	P	Р	Р		Р	Р	Р	Р		Р	
Laparoscopic	22. 2. 2. 19								Store Scheduler		10000
Pediatric											
Small Organ (Specify)						1					
Neonatal Cephalic				4							
Adult Cephalic				281							
Trans-rectal		1077-01-1010-0	1								
Trans-vaginal					A VI - A VI - A VI - A VI						
Trans-urethral											
Trans-esoph. (non-Card.)			No. 28-3UN	Contraction of the	Reference States			Con a constant			1 ELSTON
Musculo-skel. (Conventional)											
Musculo-skel. (Superficial)											0.000
Intra-luminal		- North I		ri Ventina	No. of State	in the second	Participation of the	See as Shek			0.000
Other (Specify)											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)					ENGLASSING N						
Other (Specify)											1
Peripheral vessel											

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

Additional Comments:

1) Mode combinations:

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

2) Intra-operative: Gall Bladder

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

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

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

System: bk2300 (bk5000)

Transducer: 9066 (I12C4f)

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

Clinical Application						Modes					12622.0
Specific (Tracks I & III)	В	М	PWD	CWD	Tissue Harmonic Imaging	CHI 3)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal		1									
Abdominal											
Intra-operative (Specify 2)	P	P	Р	1899	Р	Р	Р	Р		Р	P 4)
Intra-operative (Neuro)											1
Laparoscopic		12								-States and	1022
Pediatric					1						
Small Organ (Specify)											
Neonatal Cephalic											
Adult Cephalic					WWW SAMELENES						
Trans-rectal						141 1495					
Trans-vaginal									ANG 201 COMPLETE S		
Trans-urethral											
Trans-esoph. (non-Card.)		RECTORE T	Constant and		The second second		Assure 2570				1
Musculo-skel. (Conventional)											
Musculo-skel. (Superficial)									A		
Intra-luminal					1.		a the second second				
Other (Specify)											
Cardiac Adult											
Cardiac Pediatric											
Trans-esoph. (Cardiac)			STORA SHEET		E CONTRACTOR						
Other (Specify)						0.00					
Peripheral vessel											

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

Additional Comments:

1) Mode combinations:

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

- 2) Intra-operative: Liver, Biliary, Pancreas, Kidney, Stomach
- 3) Contrast Harmonic Imaging (CHI)/Contrast Imaging (CI): Previously cleared in K143298
- 4) Elastography: Previously cleared in K143298

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

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

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

System: bk2300 (bk3000)

Transducer: 9067 (E14C4)

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

Clinical Application									
Specific (Tracks I & III)	В	M	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify )									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric									
Small Organ (Specify)									10.100
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	P	Р	Р	Р	Р	Р		Р	P 2)
Trans-vaginal	Р	P	Р	Р	Р	Р		Р	P 2)
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skel. (Conventional)									
Musculo-skel. (Superficial)						s			
Intra-luminal									
Other (Specify)									
Cardiac Adult				2	110 S 12L				
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel									
Other (Specify)									

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

Additional Comments:

1) Mode combinations:

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

2) Elastography: Previously cleared in K143298

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

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

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

System: bk2300

Transducer: 9070 (18L5)

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

Clinical Application									
Specific (Tracks I & III)	В	М	PWD	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify )									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	Р	Р	Р	Р	Р		Р	P 3)
Small Organ (Specify) 2)	P	Р	Р	Р	Р	Р		Р	P 3)
Neonatal Cephalic									
Adult Cephalic								0	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)	States and the second second								
Musculo-skel. (Conventional)	P	Р	Р	Р	Р	Р		Р	P 3)
Musculo-skel. (Superficial)	Р	P	Р	Р	Р	Р		Р	P 3)
Intra-luminal									
Other (Specify)									1943
Cardiac Adult									
Cardiac Pediatric									
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vessel	Р	Р	Р	Р	Р	Р		Р	P 3)
Other (Specify)							a		

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

Additional Comments:

1) Mode combinations:

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

2) Small Organ: thyroid, breast, testes, superficial anatomy.

3) Elastography: Previously cleared in K143298

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### 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)	В	М	PWD	CWD 2)	Tissue Harmonic Imaging	Contrast Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic										100 000 000	-
Fetal											
Abdominal	P	P	Р	P	Р		Р	Р		Р	
Intra-operative (Specify)											
Intra-operative (Neuro)											
Laparoscopic			Par Stra		1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1			S. A. Statistics	Contraction of the second	CONTRACTOR NO.	
Pediatric											
Small Organ (Specify)											
Neonatal Cephalic											-
Adult Cephalic	Р	Р	Р	Р	Р		Р	Р		Р	-
Trans-rectal											
Trans-vaginal											
Trans-urethral						100.000					
Trans-esoph. (non-Card.)	Se Wind					STATE AND ST		C. March Street			
Musculo-skel. (Conventional)											
Musculo-skel. (Superficial)											
Intra-luminal				STATE STATE			200 200	S. Marchard			20.57
Other (Specify)											
Cardiac Adult	P	Р	Р	Р	Р		Р	Р		Р	
Cardiac Pediatric											
Trans-esoph. (Cardiac)	1941 (S-26-20)	1000	12.257.24		Contraction of the second	Carl March 199		States and share	in a second second		and the
Other (Specify)											
Peripheral vessel)											
Other (Specify)											

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

Additional Comments:

1) Mode combinations:

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

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

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#### 7. 510(k) Summary

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

A. Submitter's information

Name:	BK Medical ApS
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	Denmark
FDA Establishment Owner /	9680269
<b>Operator Number:</b>	
Contact person:	Karen Provencher
Phone:	978-326-4668
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Manufacturer:	BK Medical ApS
	Mileparken 34
	Herlev 2730
	Denmark
Device Name:	

B.

**Trade/Proprietary Name:** bk2300 **Common Name: Classification name: Regulation Medical Specialty: Review Panel: Product Code: Regulation Number: Device Classification:** 2 Submission type:

Ultrasound system Doppler Imaging System and Ultrasonic Pulsed Echo Radiology Radiology IYN, IYO, ITX 892.1550, 892.1560, and 892.1570 Traditional 510(k)

### C. Substantial Equivalence:

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

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



Analogic Ultrasound Group

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

## D. Device Description/Indications for Use:

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

The transducers are all multi-frequency transducers including:

- Phased Linear Array
- Convex/Curved linear array.

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

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

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

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

#### **Indications for Use:**

The system is a diagnostic ultrasound imaging system used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow analysis and puncture and biopsy guidance.

The clinical applications and exam types include: Fetal (including Obstetrics), Abdominal, Pediatric, Small Organ (also known as Small Parts), Adult Cephalic (also known as Adult Trans cranial), Neonatal Cephalic, Intraoperative, Intraoperative (Neuro), Trans rectal, Transvaginal, Transurethral, Musculoskeletal (Conventional and Superficial), Cardiac Adult, Trans-esophageal Cardiology, and Peripheral Vessel (also known as Peripheral Vascular).

Contraindications:

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



# **Options:**

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

## E. Technological Characteristics

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

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

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

The system complies with the following voluntary standards:

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