DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

BK Medical APS
% Mr. Michael J. Doyle
Global Director Regulatory & Clinical Affairs
Mileparken 34
Herlev DK-2730
DENMARK

September 16, 2015

Re: K152052
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: August 28, 2015
Received: August 31, 2015

Dear Mr. Doyle:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K152052

Device Name
Ultrasound Scanner System bk2300

Indications for Use *(Describe)*
Ultrasound scanner and transducers for B, Tissue and Contrast Harmonic Imaging, M, PWD, CWD, Color Doppler, Vector Flow Imaging and combined mode imaging and Elastography.

Signal Analysis.

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

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

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

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

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

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

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

Diagnostic Ultrasound Indications for Use Form

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

System: bk2300

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD 25)	Tissue Harmonic Imaging	Contrast Harmonic Imaging 26)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)	P	P	P	P	P	P	P	P		P	P24)
Abdominal 3)	P	P	P	P	P	P	P	P		P	P24)
Intra-operative (Specify 4)	P	P	P	P	P	P	P	P		P	P24)
Intra-operative (Neuro 5)	P	P	P	P	P	P	P	P		P	P24)
Laparoscopic 6)											
Pediatric 7)	P	P	P	P	P	P	P	P		P	P24)
Small Organ (Specify 8)	P	P	P	P	P	P	P	P		P	P24)
Neonatal Cephalic 9)	P	P	P	P	P	P	P	P		P	P24)
Adult Cephalic 10)	P	P	P	P	P	P	P	P		P	P24)
Trans-rectal 11)	P	P	P	P	P	P	P	P		P	P24)
Trans-vaginal 12)	P	P	P	P	P	P	P	P		P	P24)
Trans-urethral 13)	P	P	P	P	P	P	P	P		P	P24)
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	P	P	P	P	P	P	P	P		P	P24)
Musculo-skel. (Superficial 16)	P	P	P	P	P	P	P	P		P	P24)
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)	P	P	P	P	P	P	P	P		P	
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	P	P	P	P	P	P	P	P		P	P23) P24)
Other (Specify 24)											P
Other (Specify 25)											25)

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

The numbering in the table above refers to the comments provided below. Note that the numbering 1 to 25 is fixed to make the document more consistent meaning that comments are only provided in the table below if relevant.

Additional Comments:

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

23) Vector Flow Imaging (VFI)
24) Elastography
25) Battery

(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)

8. 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
Address:	Mileparken 34, DK-2730 Herlev, Denmark
FDA Establishment Owner/Operator Number:	9680269
Contact Person:	Michael Doyle Global Director Regulatory & Clinical Affairs
Phone:	(978) 326 - 4410
Fax:	(978) 977 - 6811
Manufacturer:	Analogic Corporation 8 Centennial Drive Peabody, MA 01960 United States
FDA Establishment Registration Number:	1220672

B. Device Name:

Trade/Proprietary Name:	Ultrasound Scanner System bk2300
Device:	System, Imaging, Pulsed Doppler, Ultrasonic System, Imaging, Pulsed Echo, Ultrasonic Transducer, Ultrasonic, Diagnostic
Regulation Description:	Ultrasonic Pulsed Doppler Imaging Ultrasonic pulsed echo imaging system Diagnostic ultrasonic transducer
Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	IYO IYN ITX
Submission Type:	Special 510(k)

Regulation Number:	892.1550 892.1560 892.1570
Device Class:	2

C. Substantial Equivalence:

The proposed Ultrasound Scanner System bk2300 with the addition of an optional system with an alternate power source (battery) solution is substantially equivalent to the identified predicates. .

D. Device Description/Indications for Use:

Ultrasound Scanner System bk2300 with the addition of an optional system with an alternate power source (battery) solution is intended for the diagnostic ultrasound imaging or fluid flow analysis of the human body and includes the following: ultrasound scanner and transducers for B, Tissue and Contrast Harmonic Imaging, M, PWD, CWD, Color Doppler, Vector Flow Imaging and combined mode imaging and Elastography.

Signal Analysis.

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

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

Transducers

All the transducers in this submission have been previously cleared. There are no changes to the physical design of the transducers or the patient contact materials. Existing transducer patient contact materials are considered biocompatible. All transducers used together with Ultrasound Scanner System bk2300 are Track 3 transducers.

Acoustic output

The system controlling the Acoustic Output in the Ultrasound Scanner System bk2300 is the same as the predicate devices. The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta $\leq$ 720 mW/cm² and MI < 1.9 (Track 3, non-ophthalmic).

The Thermal Index values are maximum 6.0, i.e. TI $\leq$ 6.0

Clinical measurement accuracy

Clinical measurements, calculations, and accuracies are described in the Ultrasound Scanner System bk2300 user Information.

Thermal, mechanical and electrical safety

The Ultrasound Scanner System bk2300 has been tested by a recognized Certified Body.

Acoustic Output Reporting

The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 9, 2008".