April 11, 2023

BK Medical Aps
% Inesa Cernajute
SR Regulatory Affairs Specialist
Mileparken 34
Herlev, 2730
DENMARK

Re: K223830
Trade/Device Name: Ultrasound System 2300
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: March 3, 2023
Received: March 3, 2023

Dear Inesa Cernajute:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph. D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223830

Device Name
Ultrasound System 2300

Indications for Use *(Describe)*

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.

Indications to Use:
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).

Modes of Operation:
- 2D (B-Mode) including Tissue Harmonic Imaging
- M-Mode
- PWD Mode
- CFM Mode (C, VFI)
- Power Doppler
- Contrast Imaging
- CW Doppler
- Strain Elastography

Environment:
The Ultrasound System 2300 is intended for use in the professional healthcare environment (e.g. hospitals, physician offices)

Contraindications:
The Ultrasound System 2300 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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K223830

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. **Submitter:** BK Medical ApS
Mileparken 34
Herlev 2730
Denmark

Manufacturer: BK Medical ApS
Mileparken 34
Herlev 2730
Denmark

Primary Contact Person: Inesa Cernajute
Senior Regulatory Affairs Specialist
BK Medical
Tel: +45 42277733
E-mail: inesa.cernajute@ge.com

Date Prepared: April 5, 2023

II. **Device Names / Common Names / Classification Names:**

Trade Names:	**Ultrasound System 2300**
Common Name:	**Ultrasound System**
Classification Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN (primary), IYO, ITX (secondary)
Class:	II
Regulation Number:	21 CFR §892.1550, §892.1560, §892.1570
Classification Panel:	Radiology

III. Identification of Predicate or Legally Marketed Devices:

- Predicate device: Ultrasound System 2300 as cleared under 510(k) premarket notification No K222441.

Trade Name:	**Ultrasound System 2300**
Common Name:	**Ultrasound System**
Classification Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN (primary), IYO, ITX (secondary)
Class:	II
Regulation Number:	21 CFR §892.1550, §892.1560, §892.1570
Classification Panel:	Radiology

IV. Device Description

The Ultrasound System 2300 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 which are offered in different configurations/ models intended for urology, general imaging, surgical and anesthesiology applications.

The system consists of a mobile console (engine) that provides digital acquisition, processing and display capabilities. The user interface includes a conventional keyboard or a glass touchpad, a 19" Clinical Display Monitor (CDM). In addition, a variety of system accessories are available such as baskets, foot switch, printer start-up kit, remote control, and extra holders.

The Ultrasound System 2300 is available in the following marketing configurations:

1. bk3000 available with a conventional keyboard configuration. The bk3000 is primarily intended for applications such as urology and general imaging

2. bk5000 available with a conventional keyboard configuration. The bk5000 is primarily intended for surgery applications.

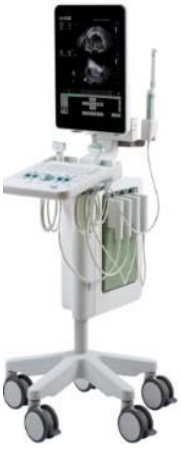
3. bkActiv is a configuration available with a glass user interface (UI). bkActiv is primarily intended for surgical, anesthesiology, urology and general imaging applications.

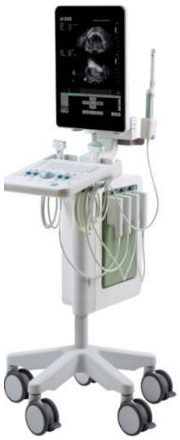
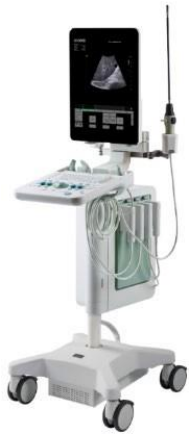
All configurations run on the previously cleared SW platform and HW platform (engine) (K222441). The various configurations of the Ultrasound System 2300 are intended to be used for different applications as described above with various transducers and options.

The primary difference between the system configurations (also refer to **Table 1**) are:

- bk5000 is the premier product offering with all features and probes available.
- bk3000 is a basic product offering with only a subset of features.
- bkActiv is a configuration available with a glass user interface (UI).

Table 1: Ultrasound System 2300 available configurations

Catalog/ Reference (REF)	**Model**		**Model Description**
2300	2300-01		BK3000 ULTRASOUND SYSTEM W/O BATTERY This configuration is primarily intended for Urology and General imaging applications.
2300	2300-11		BK3000 ULTRASOUND SYSTEM W/BATTERY This configuration is primarily intended for Urology and General imaging applications.

Catalog/ Reference (REF)	Model		Model Description
2300	2300-51		BK5000 ULTRASOUND SYSTEM W/O BATTERY This configuration is primarily intended for surgical applications.
2300	2300-61		BK5000 ULTRASOUND SYSTEM W/BATTERY This configuration is primarily intended for surgical applications.
2300	2300-56		BKACTIV ULTRASOUND SYSTEM W/O BATTERY This configuration is primarily intended for surgical, anesthesiology, urology and general imaging applications.

Catalog/ Reference (REF)	Model		Model Description
2300	2300-66		BKACTIV ULTRASOUND SYSTEM W/ BATTERY This configuration is primarily intended for surgical, anesthesiology, urology and general imaging applications.

The various configurations of the Ultrasound System 2300 are intended to be used with various multi-frequency transducers (see **Table 2**). The indicated uses are different and specific for each transducer listed.

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

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

- Surface
- Inter-operative
- Laparoscopic
- Endocavity

Table 2: Transducers used with Ultrasound System 2300 configurations

Transducer	bk3000	bk5000	bkActiv
5C1e (9085) CURVED ARRAY TRANSDUCER	X	X	X
6C2 (9040) CURVED ARRAY TRANSDUCER	X	X	X
6C2s (9023) SMALL CURVED ARRAY TRANSDUCER	X	X	X
9C2 (9002) CURVED ARRAY TRANSDUCER	X	X	X
14L3 (9051) LINEAR ARRAY TRANSDUCER	X	X	X
13L4w (9011) WIDE LINEAR ARRAY TRANSDUCER	X	X	X
10L2w (9022) WIDE LINEAR ARRAY TRANSDUCER	X	X	X
18L5 (9070) SMALL GIGH-FREQUENCY LINEAR ARRAY TRANSDUCER	X	X	X
18L5s (9081) SMALL GIGH-FREQUENCY LINEAR ARRAY TRANSDUCER	X	X	X
8L2 (9032) LINEAR ARRAY TRANSDUCER	X	X	X
E13C2 (9029) ENDFIRE ENDOCAVITY TRANSDUCER	X	X	X
E14C4t (9018) TRIPLANE ENDOCAVITY TRANSDUCER	X	X	X
X14CL4b (9048) BIPLANE ENDOCAVITY TRANSDUCER	X	X	X
E10C4 (9019) ENDOCAVITY TRANSDUCER	X	X	X
20R3 (9052) ANORECTAL TRANSDUCER	X	X	X
N13C5 (9062) CURVED ARRAY TRANSDUCER	X	X	X
5P1 (9077) PHASED ARRAY TRANSDUCER	X	X	X
X18L5S (9009) HOCKEY STICK TRANSDUCER	X	X	X
N11C5S (9063) BURR HOLE TRANSDUCER		X	X
I14C5I (9015) INTRAOPERATIVE I-SHAPE TRANSDUCER		X	X
I14C5T (9016) INTRAOPERATIVE T-SHAPE TRANSDUCER		X	X
I12C5B (9024) INTRAOPERATIVE BIPLANE TRANSDUCER		X	X
I12C5 (9034) MINI-TRANSDUCER		X	X
I12C4f (9066) LAPAROSCOPIC TRANSDUCER		X	X
X12C4 (9026) DROP-IN TRANSDUCER		X	X
X14L4 (9038) 3D ENDOCAVITY TRANSDUCER		X	X
Rob12C4 (9096) ROBOTIC TRANSDUCER		X	X
N20P6 (9007) MINIMALLY INVASIVE TRANSDUCER		X	X
I13C3f (9076) ADVANCED LAPAROSCOPIC TRANSDUCER		X	X
T7P2m (9027) TEE TRANSDUCER	X	X	X
I13C3fx (9078) ADVANCED LAPAROSCOPIC TRANSDUCER WITH TRACKING			X

V. Indications / Intended Use:

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.

Indications for Use:

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)
- Peripheral vessel (also known as Peripheral Vascular)

Modes of operation:

- B-Mode (including Tissue Harmonic Imaging)
- M-Mode
- PWD Mode
- CFM Mode (C, VFI)
- Power Doppler
- Contrast Imaging
- CW Doppler
- Strain Elastography

Environment:

The Ultrasound System 2300 is intended for use in the professional healthcare environment (e.g., hospitals, physician offices).

Contraindications

The Ultrasound System 2300 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

Table 3: Substantial Equivalence Table of the proposed device with its predicate devices

Characteristic	Ultrasound System 2300 **Proposed device (K223830)**	Ultrasound System 2300 **Predicate device**	**Comment on Comparison**
Manufacturer	BK Medical ApS	BK Medical ApS	Same
Common Name	Ultrasound System	Ultrasound System	Same
Name (Configuration models)	bk3000 (2300-01, 2300-11) bk5000 (2300-51, 2300-61) bkActiv (2300-56, 2300-66)	bk3000 (2300-01, 2300-11) bk5000 (2300-51, 2300-61) bkActiv (2300-56, 2300-66)	Same
Mode of Operation	B, M, PW, CFM, P, THI, CI, SE, CW Combination modes: 2D+M, 2D+PW, 2D+C+PW, 2D+P+PW, 2D+2D, 2D+2D (Biplane Imaging), 2D+(2D+C), 2D+(2D+P), 2D+THI, 2D+SE, 2D+CI	B, M, PW, CFM, P, THI, CI, SE, CW Combination modes: 2D+M, 2D+PW, 2D+C+PW, 2D+P+PW, 2D+2D, 2D+2D (Biplane Imaging), 2D+(2D+C), 2D+(2D+P), 2D+THI, 2D+SE, 2D+CI	Same
Intended Use	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. Indications for Use: The clinical applications and exam types include: • Fetal (including obstetrics) • Abdominal • Pediatric • Intra-operative	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. Indications for Use: The clinical applications and exam types include: • Fetal (including obstetrics) • Abdominal • Pediatric • Intra-operative	Summary of changes / comparison with predicate device - Due to the new software upgrade v. currently cleared clinical applications Cardiac Adult, Fetal (including obstetrics), Trans-rectal, Trans-vaginal, Small Organ and Peripheral vessel with transducers (9077, 9048, 9038, 9052, 9018, 9019, 9029, 9027 and 9032) previously activated on bk5000

Characteristic	Ultrasound System 2300 **Proposed device (K223830)**	Ultrasound System 2300 **Predicate device**	**Comment on Comparison**
	• 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) • Peripheral vessel (also known as Peripheral Vascular) **Modes of operation:** • 2 D (B-Mode) including Tissue Harmonic Imaging • M-Mode • PWD Mode • CFM Mode (C, VFI) • Power Doppler • Contrast Imaging • CW Doppler Strain Elastography **Environment:** The Ultrasound System 2300 is intended for use in the professional healthcare environment (e.g., hospitals, physician offices).	• 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) • Peripheral vessel (also known as Peripheral Vascular) **Modes of operation:** • 2 D (B-Mode) including Tissue Harmonic Imaging • M-Mode • PWD Mode • CFM Mode (C, VFI) • Power Doppler • Contrast Imaging • CW Doppler • Strain Elastography **Environment:** The Ultrasound System 2300 is intended for use in the professional healthcare environment (e.g., hospitals, physician offices).	/ bk3000 configurations will now also be enabled on bkActiv configuration.

Characteristic	Ultrasound System 2300 **Proposed device (K223830)**	Ultrasound System 2300 **Predicate device**	**Comment on Comparison**
	Contraindications The Ultrasound System 2300 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.	**Contraindications** The Ultrasound System 2300 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.	
Indications/Clinical Applications	• Abdominal • Intraoperative • Intraoperative – Neuro (Neurosurgery) • Pediatric • Musculo-skeletal Superficial & Conventional • Neonatal Cephalic • Adult Cephalic (Trans-cranial) • Laparoscopic • Small Organ (Small Parts) • Cardiac adult • Transesophageal (Cardiac) • Transrectal • Transvaginal • Fetal /Obstetrics • Peripheral Vessel (Vascular)	• Abdominal • Intraoperative • Intraoperative – Neuro (Neurosurgery) • Pediatric • Musculo-skeletal Superficial & Conventional • Neonatal Cephalic • Adult Cephalic (Trans-cranial) • Laparoscopic • Small Organ (Small Parts) • Cardiac adult • Transesophageal (Cardiac) • Transrectal • Transvaginal • Fetal /Obstetrics • Peripheral Vessel (Vascular)	Same

Characteristic	Ultrasound System 2300 **Proposed device (K223830)**	Ultrasound System 2300 **Predicate device (K222441)**	**Comment on Comparison**
Application Environment	Professional healthcare facility environment	Professional healthcare facility environment	Same
Users	Qualified Professional users	Qualified Professional users	Same
Patient Population	Adult, Pediatric	Adult, Pediatric	Same
Transducer types	Surface Contact Intra-operative Laparoscopic Endocavity	Surface Contact Intra-operative Laparoscopic Endocavity	Same
System Transducers	9002, 9007, 9009, 9011, 9015, 9016, 9018, 9019, 9022, 9023, 9024, 9026, 9027, 9029, 9032, 9034, 9038, 9040, 9048, 9051, 9052, 9062, 9063, 9066, 9070, 9076, 9077, 9081, 9085, 9096, 9078	9002, 9007, 9009, 9011, 9015, 9016, 9018, 9019, 9022, 9023, 9024, 9026, 9027, 9029, 9032, 9034, 9038, 9040, 9048, 9051, 9052, 9062, 9063, 9066, 9070, 9076, 9077, 9081, 9085, 9096, 9078	Transducers 9077, 9048, 9038, 9052, 9018, 9019, 9029, 9027 and 9032 currently available with bk5000/bk3000 configurations will be enabled on bkActiv configurations to support clinical applications Cardiac Adult, Fetal (including obstetrics), Trans-rectal, Trans-vaginal, Small Organ (also known as Small Parts), Peripheral vessel (also known as Peripheral Vascular).

Biocompatibility	The Ultrasound System does not come in contact with the patient.	The Ultrasound System does not come in contact with the patient.	Same
Hardware	Clinical display monitor (CDM): • 19" Optical bonded glass front. • Can be tilted and moved sideways. Cart: • adjustable height and with 4 lockable wheels Keyboard: Traditional keyboard with multiple functionalities / specialized controls or Glass touch UI Scan engine: • 4 Transducer ports • 196 TX/RX channels • Tracking Interface board	Clinical display monitor (CDM): • 19" Optical bonded glass front. • Can be tilted and moved sideways. Cart: • adjustable height and with 4 lockable wheels Keyboard: Traditional keyboard with multiple functionalities / specialized controls or Glass touch UI Scan engine: • 4 Transducer ports • 196 TX/RX channels • Tracking Interface board	Same No changes to hardware since last clearance K222441.
OS Software	Windows 10	Windows 10	Same
Associated Needle tracking accessories	UA1540 Tracking Control Unit UA1541 Portable EM Field Generator (includes field generator and a mounting solution) UA1542 Clip-on needle sensor (CIVCO) UA1543 Needle senor clamp Kit (CIVCO)	UA1540 Tracking Control Unit UA1541 Portable EM Field Generator (includes field generator and a mounting solution) UA1542 Clip-on needle sensor (CIVCO) UA1543 Needle senor clamp Kit (CIVCO)	Same

Options	- 3D Freehand - 3D Professional - DICOM Encrypted - Contrast Enhanced Ultrasound - Vector Flow Imaging (VFI) - Varian Interface - Strain Elastography - Needle Enhancement (X-shine) - BrainLab Neuro Navigation - bkFusion (for Urology Procedures) - Wi-Fi - bkViewer (SW running on a mac/windows pc) – not a medical device - Lap Ablation Navigation - **TP Needle Guide Supporting Software** - **Prostate Volume Assist (PVA)**	- 3D Freehand - 3D Professional - DICOM Encrypted - Contrast Enhanced Ultrasound - Vector Flow Imaging (VFI) - Varian Interface - Strain Elastography - Needle Enhancement (X-shine) - BrainLab Neuro Navigation - bkFusion (for Urology Procedures) - Wi-Fi - bkViewer (SW running on a mac/windows pc) – not a medical device - Lap Ablation Navigation	- Prostate Volume Assist (PVA), AI software feature which provides a workflow improvement to an existing prostate volume measurement and calculation tool. It will require the same biplane/triplane transrectal transducers (9018, 9048) that are being used for existing prostate volume calculations and measurements. Comparing to the existing prostate measurement and calculation functionality where calipers are placed manually by the user, PVA allows a faster and more efficient workflow. - In addition, proposed a new TP Needle Guide Supporting software functionality that visualizes biopsy lines for the TP Needle Guides UA1353 on the CDM (Clinical Display Monitor) to support the user having control of the needle during prostate biopsy procedure.

Characteristic	Ultrasound System 2300 **Proposed device (TBD)**	Ultrasound System 2300 **Predicate device (K222441)**	**Comment on Comparison**
Image features	Speckle reduction, compound imaging, tissue harmonic imaging (thi), contrast imaging (ci), trapezoid scanning (virtual convex) strain, elastography (se)	Speckle reduction, compound imaging, tissue harmonic imaging (thi), contrast imaging (ci), trapezoid scanning (virtual convex) strain, elastography (se)	Same
UI Design	-19-inch Clinical Monitor and touch input device for user interaction. -Trackball for cursor control. -Touchpad track pad for cursor control (Glass Touch UI) -Full configurable interaction controls (size/position)	-19-inch Clinical Monitor and touch input device for user interaction. -Trackball for cursor control. -Touchpad track pad for cursor control (Glass Touch UI) -Full configurable interaction controls (size/position)	Same

VII. Performance Data

Summary of non-clinical /Performance - Bench Testing

The proposed Ultrasound System 2300 and applied transducers, have been tested and conform to the following standards:

- ANSI/AAMI/ES 60601-: 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: Ed. 4.0, 2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-37 - Medical Electrical Equipment - Part 2-37: Ed. 2.1, 2017 Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
- IEC 62359: Ed. 2.1, 2017 - Ultrasonics - Field Characterization - Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields
- IEC 60825-1: Ed. 2.0, 2007 - Safety of laser products - part 1: equipment classification, and requirements [including: technical corrigendum 1 (2008), interpretation sheet 1 (2007), interpretation sheet 2 (2007)]
- AAMI/ANSI/ISO 10993-1: 2018 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk management Process
- AAMI TIR-12:2010 and AAMI TIR-30:2011
- IEC 62304: 2006/A1:2016 - Medical Device Software Life-Cycle Processes (Software / Informatics)
- NEMA PS3.1 – 3.20 Digital Imaging and Communications in Medicine (DICOM)
- ISO14971: 2019 - Application of risk management to medical devices

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)

- Performance testing (Verification)
- Safety testing (Verification)

AI Feature Summary of Testing – Prostate Volume Assist (PVA)

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.

- The table summarizes number of datasets used for each different purpose.

Patient Type	Training Images	Deep Learning Validation images	Test images (Clinical validation)	Comment
Healthy	505	190	975	
Diseased	13447	1189	1461	Part of the test images come from the Holland dataset, which only contributed to the test set.
Synthesized data	4104	48	0	

- Gender: Male.
- Age: patients scheduled for prostates biopsies (54 – 78 yrs) and healthy patients 30 - 60 yrs old; the specific age of each individual patient is not collected.
- Ethnicity/Country: Czech Republic, Holland. Note, European population is representative of the US population for the PVA – workflow improvement case.
- Mix of data from curved and linear arrays.
- For the testing process, the segmentation part of the algorithm is tested using a standard metric of similarity. The test passed. The final algorithm including both segmentation and caliper placement is verified by visual evaluations by clinical experts validation testing comparing the initial caliper placement by the algorithm compared to manual placement by clinical personnel. The purpose is to compare the prostate volume calculation of PVA with volume measurement performed by clinical personnel. The clinical personnel had an average of about 15 years' experience in ultrasound. We used a freeware tool developed by the Oxford Imaging Group for manual caliper placement on given images. For testing, we use two data sets that have not been part of the training of the algorithm. Data from a clinical end-user test in the Czech Republic was being used to represent the 9018 transducer and data acquired in Amsterdam, Holland, was being used to represent the 9048 transducer**.** For the latter, we generated images that correspond the scanner preset, Prostate L, as the image depth is 6.5 cm, the recommended minimum depth for PVA. The human caliper setters scored the images individually. They received the following instructions; The calipers were set in pairs corresponding to a distance measurement, so calipers 1 and 2 form one distance measurement and calipers 3 and 4 form another distance

measurement.
The validator used 2 distance measurements (using 4 calipers) on the transverse image and one distance measurement (using 2 calipers) on the sagittal image.
Acceptance criterion: the automatic initial caliper placement shall produce a prostate volume estimate that deviates no more than 22% on average from the volume estimate based on manually placed calipers.
The automatic initial caliper placement was tested with respect to prostate volume calculation accuracy and determined for the 9018 to deviate 11% +/- 6% compared to volume calculation using manual placement. The prostate volume calculation accuracy for the 9048, using the initial placement of the calipers is expected to deviate 7% +/- 15% compared to volume calculation using manual placement.

- The volumes used for test/validation purpose are completely distinct from the ones used during training process and there is no overlap between the two.

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

BK Medical ApS considers the proposed device to be as safe, as effective and performance is substantially equivalent to the predicate device(s).