BK Medical ApS
c/o Bryan Behn
Regulatory Affairs Director
Mileparken 34
Herlev, 2730
DENMARK

October 23, 2023

Re: K231764
Trade/Device Name: Ultrasound System 1300
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: September 22, 2023
Received: September 25, 2023

Dear Bryan Behn:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K231764

Device Name
Ultrasound System 1300

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

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

Modes of Operation:
• 2D (B-Mode) (including Tissue Harmonic imaging)
• M-Mode
• Vector Flow Imaging (VFI)
• Strain Elastography
• CW Doppler
• Contrast Imaging
• PWD Mode
• CFM Mode (Includes Color Doppler and Amplitude (Power) Doppler)

Environment:
The Ultrasound System 1300 is intended for use in the professional healthcare environment (e.g. hospitals, physician offices)

Contraindications:
The Ultrasound System 1300 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.

K231764

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
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BK Medical
Tel: +45 42277733
E-mail: inesa.cernajute@ge.com

Date Prepared: October 18, 2023

II. Device Names / Common Names / Classification Names:

Trade Names:	**Ultrasound System 1300**
Common Name:	**Ultrasound System**
Classification Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN (primary), IYO, ITX, QIH (secondary)
Class:	II
Regulation Number:	21 CFR §892.1550, §892.1560, §892.1570
Classification Panel:	Radiology

III. Identification of Predicate or Legally Marketed Devices:

- Primary predicate device: Ultrasound System 1300 as cleared under 510(k) premarket notification No K173569.

Trade Name:	**Ultrasound System 1300**
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

- Reference predicate device: Ultrasound System 2300 as cleared under 510(k) premarket notification No K223830.

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

The Ultrasound system 1300 is marketed under the marketing name bkSpecto

IV. Device Description

The Ultrasound System 1300 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 system consists of a mobile console (engine) that provides digital acquisition, processing and display capabilities. The user interface includes a glass touchpad, a 19" Clinical display monitor (CDM). In addition to this a variety of system accessories are available such as baskets, foot switch, printer start-up kit, and extra holders.

Table 1: Ultrasound System 1300

Catalog/ Reference (REF)	**Model**		**Model Description**
1300	1300-21		Model with rechargeable battery
1300	1300-25		Model without rechargeable battery

The various configurations of the Ultrasound System 1300 are intended to be used with various multi-frequency transducers (see **Table 2**). The indicated uses are different and specific for each transducer listed.

Table 2: Transducers used with Ultrasound System 1300

Name Description	#Reference
ENDOCAVITY TRANSDUCER **E10C4**	9019
BIPLANE ENDOCAVITY TRANSDUCER **E11C3b**	9008
TRIPLANE ENDOCAVITY TRANSDUCER **E14C4t**	9018
ENDFIRE ENDOCAVITY TRANSDUCER **E13C2**	9029
BIPLANE ENDOCAVITY TRANSDUCER **E14CL4b**	9048
CURVED ARRAY TRANSDUCER **9C2**	9002
SMALL CURVED ARRAY TRANSDUCER **6C2s**	9023
CURVED ARRAY TRANSDUCER **6C2**	9040
CURVED ARRAY TRANSDUCER **5C1e**	9085
PHASED ARRAY TRANSDUCER **5P1e**	9087
HOCKEY STICK TRANSDUCER **X18L5s**	9009
WIDE LINEAR ARRAY TRANSDUCER **13L4w**	9011
LINEAR ARRAY TRANSDUCER **8L2**	9032
LINEAR ARRAY TRANSDUCER **14L3**	9051
HIGH-FREQUENCY LINEAR ARRAY TRANSDUCER **18L5**	9070
HIGH-FREQUENCY LINEAR ARRAY TRANSDUCER **18L5s**	9081
LINEAR ARRAY TRANSDUCER **14L3e**	9086
3D ENDOCAVITY TRANSDUCER **X14L4**	9038
ANORECTAL TRANSDUCER **20R3**	9052
I-SHAPED INTRAOPERATIVE TRANSDUCER I14C5I	9015
T-SHAPED INTRAOPERATIVE TRANSDUCER I14C5T	9016
BIPLANE INTRAOPERATIVE TRANSDUCER I12C5b	9024
ROBOTIC DROP-IN TRANSDUCER X12C4	9026
CURVED ARRAY CRANIOTOMY TRANSDUCER N13C5	9062
BURR HOLE TRANSDUCER N11C5s	9063

V. Indications / Intended Use:

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 (cephalic is also known as Adult trans-cranial), Neonatal Cephalic, Intra-operative, Intra-operative Neuro (also known as Neurosurgery), Trans-rectal, Trans-vaginal, Musculo-skeletal (Conventional and Superficial), Cardiac Adult, and Peripheral Vessel (also known as Peripheral Vascular).

Modes of Operation:
- 2D (B-Mode) (including Tissue Harmonic imaging)
- M-Mode
- Vector Flow Imaging (VFI)
- Strain Elastography
- CW Doppler
- Contrast Imaging
- PWD Mode
- CFM Mode (Includes Color Doppler and Amplitude (Power) Doppler)

Environment:
The Ultrasound System 1300 is intended for use in the professional healthcare environment (e.g. hospitals, physician offices).

Contraindications:
The Ultrasound System 1300 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 1300 **Proposed device (K231764)**	Ultrasound System 1300 **Primary Predicate (K173569)**	**Comment on Comparison**
Manufacturer	BK Medical ApS	BK Medical ApS	Same
Common Name	Ultrasound System	Ultrasound System	Same
Name (Configuration models)	bkSpecto (1300-21, 1300-25)	bkSpecto (1300-21)	Added: - bkSpecto 1300-25- a model without battery. - Prostate Volume Assist (PVA), AI software feature.
Mode of Operation	B, M, PW, CFM, P, THI, 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 (B-Mode) (including Tissue Harmonic imaging) • M-Mode • Vector Flow Imaging (VFI)	B, M, PW, CFM, P, THI, 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 (B-Mode) (including Tissue Harmonic imaging) • M-Mode • Vector Flow Imaging (VFI)	Same – primary predicate Equivalent – ref. predicate

Characteristic	Ultrasound System 1300 **Proposed device (K231764)**	Ultrasound System 1300 **Primary Predicate (K173569)**	**Comment on Comparison**
	• Strain Elastography • CW Doppler • Contrast Imaging • PWD Mode • • CFM Mode (Includes Color Doppler and Amplitude (Power) Doppler)	• Strain Elastography • CW Doppler • Contrast Imaging • PWD Mode • • CFM Mode (Includes Color Doppler and Amplitude (Power) Doppler)	
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. Environment: The Ultrasound System 1300 is intended for use in the professional healthcare environment (e.g., hospitals, physician offices). Contraindications: The Ultrasound System 1300 is not intended for ophthalmic use or any 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. Environment: The Ultrasound System 1300 is intended for use in the professional healthcare environment (e.g., hospitals, physician offices). Contraindications: The Ultrasound System 1300 is not intended for ophthalmic use or any use	Same

Characteristic	Ultrasound System 1300 **Proposed device (K231764)**	Ultrasound System 1300 **Primary Predicate (K173569)**	**Comment on Comparison**
	causing the acoustic beam to pass through the eye. The Cardiac Adult application is not intended for direct use on the heart.	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	• Fetal (including Obstetrics) • Abdominal • Pediatric1 • Intraoperative1,2 • Intraoperative Neuro (also known as Neurosurgery)1 • Small Organ (Small Parts)3 • Adult Cephalic (cephalic is also known as Adult trans-cranial)1 • Neonatal Cephalic1 • Transrectal • Transvaginal • Musculoskeletal (Conventional) • Musculoskeletal (Superficial) • Cardiac Adult • • Peripheral Vessel (Peripheral Vascular))	• Fetal (including Obstetrics) • Abdominal • Pediatric1 • Intraoperative1,2 • Intraoperative Neuro (also known as Neurosurgery)1 • Small Organ (Small Parts)3 • Adult Cephalic (cephalic is also known as Adult trans-cranial)1 • Neonatal Cephalic1 • Transrectal • Transvaginal • Musculoskeletal (Conventional) • Musculoskeletal (Superficial) • Cardiac Adult • • Peripheral Vessel (Peripheral Vascular)	Identical

Characteristic	Ultrasound System 1300 **Proposed device (K231764)**	Ultrasound System 1300 **Primary Predicate (K173569)**	**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 Endocavity Intraoperative	Surface Endocavity Intraoperative	Identical
System Transducers	9002, 9008, 9009, 9011, 9015, 9016, 9018, 9019, 9023, 9024, 9026, 9029, 9032, 9038, 9040, 9048, 9051, 9052, 9062, 9063, 9070, 9081, 9085, 9086, 9087	9002, 9008, 9009, 9011, 9015, 9016, 9018, 9019, 9022, 9023, 9024, 9026, 9029, 9032, 9038, 9040, 9048, 9051, 9052, 9062, 9063, 9067, 9070, 9081, 9085, 9086, 9087	Since 2017 the following transducers have been terminated:9022 and 9067
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: Glass touch UI	Clinical display monitor (CDM): • 19" Optical bonded glass front. • Can be tilted and moved sideways. Cart: • adjustable height and with 4 lockable wheels Keyboard: Glass touch UI	Same – primary predicate Equivalent – ref. predicate

Characteristic	Ultrasound System 1300 **Proposed device (K231764)**	Ultrasound System 1300 **Primary Predicate (K173569)**	**Comment on Comparison**
	Scan engine: • 3 Transducer ports • 64 TX/RX channels	Scan engine: • 3 Transducer ports 64 TX/RX channels	
OS Software	Windows 10	Windows 8.1 Industrial	Updated to Windows 8 OS to Windows 10.
Options	- 3D Freehand - 3D Professional - DICOM Encrypted - Vector Flow Imaging (VFI) - Varian Interface - Strain Elastography - Needle Enhancement (X-shine) - Wi-Fi - bkViewer (SW running on a mac/windows pc) – not a medical device - Prostate Volume Assist (PVA)	- 3D Freehand - 3D Professional - DICOM Encrypted - Vector Flow Imaging (VFI) - Varian Interface - Strain Elastography - Needle Enhancement (X-shine) - Wi-Fi	- Proposed a new Prostate Volume Assist (PVA), AI software feature that has been recently cleared under K223830 for the Reference Predicate device Ultrasound System 2300. PVA provides a workflow improvement to an existing prostate volume measurement and calculation tool. It will require the same biplane/triplane transrectal transducers (9008, 9018, 9048) that are being used for existing prostate volume calculations and measurements.
Image features	Speckle reduction, compound imaging, tissue harmonic imaging (thi), trapezoid scanning (virtual convex) strain, elastography (se)	Speckle reduction, compound imaging, tissue harmonic imaging (thi), trapezoid scanning (virtual convex) strain, elastography (se)	Same

Characteristic	Ultrasound System 1300 **Proposed device (K231764)**	Ultrasound System 1300 **Primary Predicate (K173569)**	**Comment on Comparison**
UI Design	-19-inch Clinical Monitor and touch input device for user interaction. -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. -Touchpad track pad for cursor control (Glass Touch UI) -Full configurable interaction controls (size/position)	Same – primary predicate Equivalent – ref. predicate
Standards	ELECTROMAGNETIC COMPATIBILITY Complies with requirements for Class A devices of IEC 60601-1-2 SAFETY ANSI/ AAMI/ES 60601-1, IEC 60601-2-37 SOFTWARE/ FIRMWARE IEC62304 CLEANING VALIDATION AAMI TIR12, AAMI TIR30 DICOM NEMA PS3.1-3.20 Digital Imaging and Communications in Medicine (DICOM)	ELECTROMAGNETIC COMPATIBILITY Complies with requirements for Class A devices of IEC 60601-1-2 SAFETY ANSI/ AAMI/ES 60601-1, IEC 60601-2-37 SOFTWARE/ FIRMWARE IEC62304 CLEANING VALIDATION AAMI TIR12, AAMI TIR30 DICOM NEMA PS3.1-3.20 Digital Imaging and	Same – primary predicate Equivalent – ref. predicate

Characteristic	Ultrasound System 1300 **Proposed device (K231764)**	Ultrasound System 1300 **Primary Predicate (K173569)**	**Comment on Comparison**
		Communications in Medicine (DICOM)	

VII. Performance Data

Summary of non-clinical /Performance - Bench Testing

The proposed Ultrasound System 1300 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
- 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	Includes images from Holland dataset that are only used as Test images.
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. Representing the 9018, we clinical end-user test in the Czech Republic and representing the 9048 using data acquired by in Amsterdam, Holland. 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. The automatic initial placement was tested and determined for the 9018 and 9008 to deviate 11% +/- 6% compared to manual placement and for the 9048, the initial placement of the caliper is expected to deviate 7% +/- 15% compared to 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).