K132335
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Attachment 4

510(k) Summary:

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

JAN 10 2014

Submitters name: B-K Medical
Address: Mileparken 34, 2730 Herlev, Denmark
Phone: +45 44528100
Fax: +45 44528199
Contact person: Randi Hauerberg, Regulatory Affairs Lead Manager
Date prepared: July 3, 2013

Trade name: Ultrasound Scanner Flex Focus 1202
Common name: Diagnostic Ultrasound System
Classification names:

Ultrasonic Pulsed Echo Imaging System	(90 IYO, CFR 892.1560)
Ultrasonic Pulsed Doppler Imaging System	(90 IYN, CFR 892.1560)
Diagnostic Ultrasonic Transducer	(90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:
B-K Medical Ultrasound Scanner Flex Focus 1202, K081154
B-K Medical Ultrasound Scanner Flex Focus 1202, K123254

Device description:

Flex Focus 1202 supports the following scanning modes and combinations thereof:
B-mode (incl.Tissue Harmonic Imaging), M-mode, PWD mode, CFM mode, Amplitude (Power) Doppler mode.

The system can perform simple geometric measurements, and perform calculations in the areas of Vascular, Urology, Cardiology and OB/GYN applications.

The system can guide biopsy- and puncture needles.

An optional 3-D module 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.

An optional RF wireless function with the ability to wireless transmit for printing and archive connectivity purpose.

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Transducers
Transducers are linear arrays, convex arrays, phased arrays and mechanical sector.
The patient contact materials are biocompatible.
All transducers used together with Flex Focus 1202 are Track 3 transducers.

Acoustic output
The system controlling the Acoustic Output in the modified Flex Focus 1202 is the same as the system in Flex Focus 1200. The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta ≤ 720 mW/cm² and MI ≤ 1.9 (Track 3, non ophthalmic).
The Thermal Index values are maximum 6.0, i.e. TI ≤ 6.0

Clinical measurement accuracy
Clinical measurements and calculations are described and accuracies are provided in the User Information.

Thermal, mechanical and electrical safety.
The scanner Flex Focus 1202 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"

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body.

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Summary of Technological Characteristics – Predicate Device Compared to Modified Device

	Predicate device K081154, Ultrasound scanner Flex Focus 1202	**Predicate device K123254, Ultrasound scanner Flex Focus 2202**	**Modified device (this application), Ultrasound scanner Flex Focus 1202**
Modes of operation Ref.: [1] Appendix G	B, M, PWD, CFM [1)] and combinations Tissue harmonic imaging.	B, M, PWD, CFM [1)+2)] and combinations Tissue harmonic imaging.	B, M, PWD, CFM [1)+2)+3)] and combinations Tissue harmonic imaging.
Intended Use: Indications For Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Abdominal Cardiac Fetal (incl Obstetrics) Intraoperative Transurethral Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Muskulo-skeletal (conventional and superficial)	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Abdominal Cardiac Fetal (incl Obstetrics) Intraoperative Transurethral Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Muskulo-skeletal (conventional and superficial)	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Abdominal Cardiac Fetal (incl Obstetrics) Intraoperative Transurethral Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Muskulo-skeletal (conventional and superficial)
Features			

1) CFM= Color Flow Mapping=Color Doppler and Amplitude (Power) Doppler.
2) Includes Vector Flow Imaging
3) Includes RF wireless function

A brief discussion of non-clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

The device has been evaluated for acoustic output, thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- AIUM/NEMA UD-2, Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-3, Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 60601-1, Medical Electrical Equipment, Part 1: General requirements for safety
- IEC 60601-1-1, General requirements for safety, Part 1:1, Collateral Standard, Safety requirements for medical electrical systems,

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- IEC 60601-1-2, General requirements for safety, Collateral Standard, Electromagnetic Compatibility – Requirements and tests
- IEC 60601-2-37, Particular requirements for the safety of ultrasonic diagnostic medical and monitoring equipment
- ISO 14971, Application of Risk Management of Medical Devices
- IEC 62304, Medical Device Software – Software lifecycle processes
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

Cleared patient contact materials, electrical and mechanical safety are unchanged.

Additional testing of the RF wireless function was performed at five (5) different sites representing actual user requirements. Several test scenarios was performed and no interference was measured.

Technological characteristics compared to the predicate device
The predicate device has the same major technological characteristics as the subject device described above.
Minor differences consist: Optional RF wireless function.

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

January 10, 2014

B-K Medical ApS
% Mrs. Randi Hauerberg
Regulatory Affairs Lead Manager
Mileparken 34
Herlev DK-2730
DENMARK

Re: K132335
Trade/Device Name: Ultrasound Scanner Flex Focus 1202
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN, ITX
Dated: November 29, 2013
Received: December 19, 2013

Dear Mrs. Hauerberg:

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.

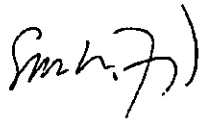
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Janine M. Morris
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): K132335

Device Name: **Ultrasound Scanner Flex Focus 1202**

Indications for Use:

Ultrasound scanner and transducers for B, Tissue and Contrast Harmonic Imaging, M, PWD,CWD, Color Doppler, Vector Flow Imaging and combined mode imaging.
Signal analysis and display.
Guidance of biopsy needles, geometrical measurements and calculation of parameters.
An optional 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.

An optional RF wireless function with the ability to wireless transmit for printing and archive connectivity purpose.

Clinical applications: Abdominal, Cardiac, Fetal, Intraoperative, Neurosurgery, Obstetrics, Pediatrics,Transrectal, Small organs, Transvaginal, Musculoskeletal.

Details on specific Indication for Use forms

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH
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(Division Sign-Off)
Division of Radiological Health/OIR
510(k) _____K132335_____

Diagnostic Ultrasound Indications for Use Form

System: 1202

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

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	Tissue-harmonic imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify 1)	Other4)
Ophthalmic										
Fetal 2) (K081154)		P	P	P	P	P	P		P	
Abdominal (K081154)		P	P	P	P	P	P		P	
Intraoperative (specify) (K081154)		P	P	P	P	P	P		P	
Intraoperative Neurological (K081154)		P	P	P	P	P	P		P	
Pediatric (K081154)		P	P	P	P	P	P		P	
Small Organ (specify) (K081154)		P	P	P	P	P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (K081154)		P	P	P	P	P	P		P	
Transesophageal										
Transrectal (K081154)		P	P	P	P	P	P		P	
Transvaginal (K081154)		P	P	P	P	P	P		P	
Transurethral (K081154)		P	P	P	P	P	P		P	
Intravascular										
Peripheral Vascular (K081154), (K123254 [3])		P	P	P	P	P[3)]	P		P	
Laparoscopic										
Musculo-skeletal Conventional (K081154)		P	P	P	P	P	P		P	
Musculo-skeletal Superficial (K081154)		P	P	P	P	P	P		P	
Other (specify) RF Wireless										N[4)]

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

Additional Comments: 1) B+M, B+D, B+C, B+D+C.
B mode includes Tissue Harmonic Imaging

D is PWD, C is Color Doppler.

2) Fetal is often called Obstetrics

3) Vector Flow Imaging

4) RF wireless function

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

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