K132677
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JAN - 7 2014

510(k) Summary:

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

Submitters name: B-K Medical
Address: Mileparken 34, DK2730 Herlev, Denmark
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Contact person: Gert Nielsen, Regulatory Manager
Date updated: November 01, 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:
The predicate device(s) is(are):

ZONARE Medical Systems Inc.:
ZONARE ZS3 Ultrasound System (K120703)
Transducer Model Number: C10-3

- **Philips Healthcare, Inc.:**
  CX50 Diagnostic Ultrasound System (K111513)
  Transducer Type: C8-5
- **Toshiba America Medical Systems, Inc.:**
  Diagnostic Ultrasound System (K121422)
  - Aplio 500 TUS-A500 v2.1
  - Aplio 400 TUS-A400 v2.1
  - Aplio 300 TUS-A300 v2.1

  Transducer Model Number: PVT-712BT

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 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
Transducers are linear arrays, convex arrays, phased arrays and mechanical sector.

The patient contact materials are biocompatible and comply with ISO10993-1.
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 the Flex Focus 1202.
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 with the User Guide.

Thermal, mechanical and electrical safety.
The scanner 1202 has been tested by a recognized, certified body according to IEC 60601-1.

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 30, 2008"
The acoustic output is measured and calculated according to: "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (AIUM 1998).

Intended use.
See comparison below

Technological characteristics compared to the predicate device(s).
The predicate device(s) has the same major technological characteristics as the subject device, see comparison below.

Comparison with the predicate devices mentioned above from:

Supplier	BK Medical Systems	ZONARE Medical Systems	Philips	Toshiba	Comparison
510K No.	K081154,K123254	K120703	K123754	K121422	
Intended use	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows	Diagnostic Ultrasound Imaging and fluid flow analysis in the following applications:	Diagnostic Ultrasound Imaging and fluid flow analysis in the following applications.	Visualization of structures and dynamic process with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications:	Comparable
Indications for use	Abdominal Fetal (incl Obstetrics) Intraoperative Transurethral Neurosurgery Pediatrics Small Parts (organs) Neonatal Cephalic Cardiac Transrectal Transvaginal Peripheral vascular Muskulo-skeletal (conventional and superficial)	Opthalmic, Fetal/Obstetric, Gynecological, Abdominal (renal, TYN/Pelvic; Intra-operative (abdominal, thoracic, and vascular, Intra-operative neurological, Pedicatric, Small organ (thyroid, breast, testes, etc), Adult Cephalic, Neonatal Cephalic, Trans-rectal, Trans-vaginal, Trans-cranial, Trans-esophageal (non-cardiac and cardiac), Musculoskeletal (conventional & Superficial), 3D/4D, Cardiac Adult,/Pediatrics/Fetal, Echo, Intra-Cardiac, Pelvic, Perpheral vasuclar, harmonic tissue and contrast imaging and tissue elasticity, Vet and others	Opthalmic, Intracardiac echo, Intraoperative, Laparoscopic, Fetal, Abdominal, Pediatric, Small organ, Adult Cephalic, Neonatal Cephalic, Transvaginal, Musculosceletal, Gynecological, Cardiac Adult, Cardiac Pediatric, Trans-Esophogeal (Cardiac), Peripheral Vessel, Other (Carotid)	abdominal, intra-operative (abdominal), Pediatric, Small organs, Neonatal Cepahlic Adult Cephalic Trans-vaginal, Trans-rectal Musculoskeletal (conventional and superficial) Cardiac Pediatric Cardiac Adult Peripheral Vascular Transesophageal	Comparable
Transducer specific					
510K No.	K043524	K120703	K123754	K121422	
Indication for use	Neonatal Cephalic	Neonatal Cephalic	Neonatal Cephalic	Neonatal Cephalic	Comparable
Frequency range	10-3.8 MHz	10-3 MHz	8-5 MHz	10-3 MHz	Comparable

Summary of Clinical Tests:
This submission introduces no new indications for use, modes, features or technologies relative to the predicate devices that require clinical testing. The clinical safety and effectiveness of ultrasound system with these characteristics are well accepted for both predicate and subject devices.

Conclusion: The device Flex Focus 1202 and the probe N13C5 type 8862 in this application has similar intended uses, and in particular the subject for the submission, the addition of the new application **Neonatal Cephalic**, is the same.

B-K Medical ApS therefore considers, that 1202 is substantially equivalent to the predicate devices.

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 7, 2014

B-K Medical ApS
% Mr. Gert Nielsen
Regulatory Affairs Manager
Mileparken 34
Herlev DK-2730
DENMARK

Re: K132677
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: December 5, 2013
Received: December 19, 2013

Dear Mr. Nielsen:

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.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasound Scanner Flex Focus 1202, as described in your premarket notification:

Transducer Model Number

N13C5 Type 8862

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.

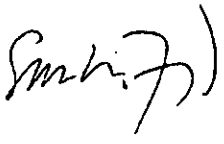
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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):
K132677

Device Name:
Ultrasound Scanner Flex Focus 1202
Ultrasound Transducer N13C5, Type 8862

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.
Non monitoring ECG for superimposing the ultrasound information.
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.

Clinical applications:
Ultrasound Scanner Flex Focus 1202:
Fetal, Obstetrics, Abdominal, Intraoperative, Neurosurgery, Small organ, Pediatric, Neonatal Cephalic, Cardiac, Transrectal, Transvaginal, Transurethral, Peripheral Vascular, Musculoskeletal.

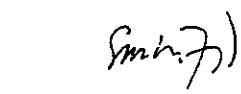
Ultrasound Transducer N13C5, Type 8862: Neonatal Cephalic.

Details on specific Indication for Use forms

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(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)



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(Division Sign-Off)
Division of Radiological Health/OIR
510(k) ___K132677_____

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)	Other 3)
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		N	N	N	N	N	N		N	
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 except other 3)) (K123254 other 3)		P	P	P	P	P	P		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)										

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.
D is PWD, C is Color Doppler.

2) Fetal is often called Obstetrics

3) Vector Flow Imaging

(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)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 1202_____
Transducer: 8862_____

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify 1)	Amplitude Doppler
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify 2) (K081154)	E	E	E		E	E	E
	Intra-operative (Neuro) (K081154)	E	E	E		E	E	E
	Laparoscopic							
	Pediatric (K081154)	E	E	E		E	E	E
	Small Organ (Specify)							
	Neonatal Cephalic	N	N	N		N	N	N
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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

Additional Comments:____1) Mode combinations: B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)_____
2)Intraoperative: Gall bladder_____

(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)