Attachment 4
K991937 7/30/99

510(k)Summary of safety and effectiveness, Ultrasound Scanner 2101

Overall description

2101 supports the following scanning modes and mode combinations:
B-mode and B+M-mode (M=motion).
An optional ECG signal can be superimposed the ultrasound information in all modes and mode combinations.
The system operates with 3 types of transducers: mechanical sector, linear array and convex array (curved linear array).
The system can perform simple geometric measurements, and perform calculations in the areas of Urology, Cardiology and OB/GYN applications.

Transducers

Transducer type	Mode	Geometrical configuration
8656	B-M	Convex Array
8660	B-M	Linear Array
8661	B-M	Convex Array
8662	B-M	Convex Array
8665	B-M	Convex Array
1880	B	Mechanical Sector

All transducers used together with 2101 are Track 3 transducers.

Intended use.

2101-intended uses are contained within 2002-intended uses:

	Predicate device, Ultrasound scanner Type 2002 (K943315)	Submitted device, Ultrasound scanner Type 2101
Modes of operation	B, M, PWD, CFM and combinations	B, M and combinations
Intended use(clinical application)	Abdominal Cardiac Fetal Doppler Intraoperative Neurosurgery Obstetrics Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular	Abdominal Cardiac Fetal 1) Intraoperative Neurosurgery Obstetrics Pediatrics Transrectal Small Parts (organs) Transvaginal
Features	ECG (not monitoring)	ECG (not monitoring)

1) Fetal application is included in Obstetrics and Transvaginal.

Controls that affect the radiated field
The system is designed and verified such, that neither the global maximum of *MI* nor the global maximum derated *Ispta* values exceed the allowable values (Track 3, non ophthalmic device).

Size function: (Size up and Size Down).
In general, smaller size gives higher acoustic intensity.
Zoom function: (Zoom in or Zoom out around a specific area).
In general, smaller zoomed areas give higher acoustic intensity through higher pulse repetition frequency.
Focus: (Strong focus and focus point selection).
In general, selecting a Focus point in combination with Strong Focus gives higher acoustic intensity.
Frame Rate:
In general, higher rate gives higher acoustic intensity.

Patient contact materials
The patient contact materials comply with ISO10993-1

Acoustic output and device settings used
The system controlling the Acoustic Output in 2101 is the same as the system in 2002. 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 Guide.

Thermal, mechanical and electrical safety.
The scanner 2101 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, 1997"
The acoustic output is measured and calculated according to: "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (NEMA 1997).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

Villy Braender
Official Correspondent
B-K Medical A/S
Sandtoften 9
DK 2820, Gentofte
DENMARK

Re: K991937
Ultrasound Scanner Type 2101
Dated: July 2, 1999
Received: July 6, 1999
Regulatory Class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Braender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasound Scanner, Type 2101, as described in your premarket notification:

Transducer Model Number

Type 1880, Type 8656, Type 8660
Type 8661, Type 8663, Type 8665

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

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If you have any questions regarding the content of this letter, please contact Robert Phillips, Ph.D. at (301) 594-1212.

Sincerely yours,

for CAPT Daniel Schultz, M.D.
Acting Director
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3

Attachment 2

Indications for Use Statement

510(k)Number:
(if known)

Device Name : **Ultrasound scanner Type 2101**

Indications for Use :

**Ultrasound scanner and transducers for B, M and combined mode imaging.
Guidance of biopsy needles, geometrical measurements and calculation of parameters.
Non monitoring ECG for superimposing the ultrasound information.**

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991937

Prescription Use _ ✓ _ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)