K081323

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
Phone: +45 44528100
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Establishment registration number: 9680269

JUL 22 2008

Contact person: Jens Rasmussen, Director of Quality
Date prepared: 9 May 2008

Trade name: Biopsy guide for 8808 (UA1257S17E), Biplane biopsy guide for 8818 (UA1322-S), Endfire biopsy guide for 8818 (UA1323-S), Dual biopsy guide for 8818 (UA1329-S).

Common name: Biopsy needle guide

Classification:
Kit, needle biopsy FCG (CFR 876.1075) Class II

Identification of predicate, legally marketed device:
Targetscan biopsy kit, Targetscan biopsy needle guide (K073399)

Device description:
The biopsy guides are designed to be used with B-K Medical's ultrasound systems to guide needles for taking biopsies of the prostate and similar soft tissue. The biopsy guides are fixed to the ultrasonic probe, and provide a predetermined path for a biopsy needle.
The biopsy guides are similar to previously used biopsy guides delivered non sterile. The new biopsy guides are delivered sterile.

Intended use.
Purpose: Performing ultrasound guided biopsies of the prostate.
Intended patient population: The intended population is adult patients.
Intended environment: The device is for use by medical professionals in a physician office or hospital environment.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 22 2008

Mr. Jens Rasmussen
Director of Quality
B-K Medical
Mileparken 34, DK-2730 Herlev
DENMARK

Re: K081323
Trade/Device Name: Biopsy guide for 8808 (UA1257S17E), Biplane biopsy guide for 8818 (UA1322-S), Endfire biopsy guide for 8818 (UA1323-S), and Dual biopsy guide for 8818 (UA1329-S)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: June 30, 2008
Received: July 7, 2008

Dear Mr. Rasmussen:

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.

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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K081323

Indications for Use

510(k) Number (if known): **K081323** _____

Device Name:

Biopsy guide for 8808 (UA1257S17E), Biplane biopsy guide for 8818 (UA1322-S), Endfire biopsy guide for 8818 (UA1323-S), Dual biopsy guide for 8818 (UA1329-S)

Indications for Use:

Performing ultrasound guided biopsies of the prostate

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K081323