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K050135

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Summary of Safety and Effectiveness Information

Submitter Information:

Submitter's Name: Address:	Bioengineering Consultants ltd. 801 West Main Street Charlottesville, VA 22903
Phone Number:	434-979-4134 434-979-5725 fax
Contact Person:	William R. Krause

Device Name:

Trade Name:	K-C Hemostatic Biopsy System
Common/Usual Name:	Biopsy device

Classification:

Class:	Class II, per CFR Part 876.1075
Name:	Gastroenterology-urology biopsy instrument, needle
Product Code	KNW

Performance Standards:

The FDA under Section 514 of the Food and Drug and Cosmetic Act has not established Performance Standards.

Indications for Use:

The K-C Hemostatic Biopsy System is indicated for use endoscopically or percutaneous to retrieve tissue sampling of soft organs/tumors or masses for histological analysis and deliver a hemostatic material to the biopsy site to reduce bleeding from the biopsy site. Soft tissue sampling includes but not limited to organs such as breast, liver, kidney and prostate. It is not intended for use in bone.

Device Description:

The proposed device consists of a mechanism to capture a biopsy sample of soft tissue, soft organs, tumor or masses for histological analysis and a co-axially configured syringe containing a hemostatic agent to be delivered into the biopsy tract upon removal of the biopsy sample.

Technological Characteristics:

The intended use, design, operating principles and materials are similar to devices previously cleared via the 510(k) process.

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Substantial Equivalence:

The K-C Hemostatic Biopsy System has been tested and compared to substantially equivalence, predicative devices listed below. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.

Predicative Devices

Hemostatic Delivery Devices:
QuickSeal Arterial Closure System
Sub-Q Inc. (San Clemente, CA)
FDA # P010049

Aspiration Needles

a. Modified MENGHINI Needle for Aspiration Biopsy
Becton Dickerson and Company(Franklin Lakes, NJ):

b. Jamshidi Menghini soft Tissue Biopsy Tray Allegiance Healthcare Corporation (McGaw Park, IL)

c. Jamshidi Soft Tissue Biopsy Needle/Syringe Baxter Healthcare Corp.(Valencia, CA)

Cutting Needles

a. Bard Max-Core Disposible Biopsy System
CR Bard (Murray Hill, NJ)

b. Temno Biopsy System
Cardinal Health Corporation (McGaw Park, IL)

c. Coaxial Quick-Core Biopsy Sets
Cooke Inc. (Bloomington, IN)

d. ASAP™ Automated Biopsy System
Boston Scientific (Watertown, MA)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2005

William R. Krause, Ph.D.
President
Bioengineering Consultants, Ltd.
801 West Main Street
Charlottesville, Virginia 22903

Re: K050135
Trade/Device Name: K-C Hemostatic Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: May 4, 2005
Received: May 10, 2005

Dear Dr. Krause:

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 (PMA), 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 Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050135

Device Name: K-C Hemostatic Biopsy System

Indications For Use: The K-C Hemostatic Biopsy System is indicated for use endoscopically or percutaneously to retrieve tissue sampling of soft organs/tumors or masses for histological analysis and deliver a hemostatic material to the biopsy site to reduce bleeding from the biopsy site. Soft tissue sampling includes but not limited to organs such as breast, liver, kidney and prostate. It is not intended for use in bone.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 General, Restorative
and Neurological Devices

510(k) Number K050135