



Food and Drug Administration
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May 1, 2015

Covidien, LLC
Saket Bhatt
Regulatory Affairs Manager
540 Oakmead Parkway
Sunnyvale, CA 94085

Re: K150891
Trade/Device Name: BNX™ Fine Needle Aspiration System
Product Code: FCG, NEU
Trade/Device Name: SharkCore™ Fine Needle Biopsy System
Product Code: FCG

Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Dated: April 1, 2015
Received: April 2, 2015

Dear Saket Bhatt,

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
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510(k) Number (if known)
 K150891

Device Name
 BNX Fine Needle Aspiration System and the SharkCore Fine Needle Biopsy System

Indications for Use (Describe)

BNX Fine Needle Aspiration System: The device is used to sample targeted sub-mucosal and extramural gastrointestinal lesions through the accessory channel of an ultrasound endoscope. The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needle sticks. The 19Ga. and 22Ga. BNX™ ASPIRATION Needles are also intended to implant fiducial markers under endoscopic ultrasound to radiographically mark soft tissue for future therapeutic procedures.

SharkCore Fine Needle Biopsy System: The device is used with an ultrasound endoscope for fine needle biopsy (FNB) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract. The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needle sticks.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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This 510(k) Summary for BNXTM Fine Needle Aspiration System and SharkCoreTM Fine Needle Biopsy System is being submitted in accordance with 21 CFR 807.92.

Submitter's Name and Address: Covidien llc
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Phone : 408-328-7357
Fax : 408-328-7357 (same as phone #)

Date: April 1, 2015

Name of Medical Device: Device Regulation: 21 CFR 876.1075, Class II
Product Code: FCG for SharkCore Fine Needle Biopsy System
FCG and NEU for BNX Fine Needle Aspiration System
Common/Usual Name: Kit, Needle, Biopsy
Proprietary Name: BNX Fine Needle Aspiration System / SharkCore Fine Needle Biopsy System
Classification Panel: Gastroenterology-Urology Devices Panel

Predicate Devices: The modified BNX EUS FNA is substantially equivalent to the BNX Fine Needle Aspiration System cleared in K142198 (October 8, 2014).

The modified SharkCore EUS FNB is substantially equivalent to the SharkCoreTM EUS FNB cleared in K141894 (October 6, 2014).

Device Description: The BNX FNA / SharkCore FNB Systems are sterile, single patient use endoscopic ultrasound aspiration needles. The devices consists of the Beacon TM Endoscopic Ultrasound Delivery System and either the BNX Fine Needle Aspiration Needle or the SharkCore Fine Needle Biopsy Needle which are assembled before insertion through the accessory channel of an ultrasound endoscope. The devices are offered with needle sizes of 19, 22 and

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25 gauge. The BNX FNA / SharkCore FNB Systems have an integrated needle protection shield that automatically engages over the distal end of the needle during removal to cover the needle sharp. In this manner, the needle tip is covered to help protect against inadvertent needle sticks.

Indications For Use:

BNX Fine Needle Aspiration System: The device is used to sample targeted sub-mucosal and extramural gastrointestinal lesions through the accessory channel of an ultrasound endoscope. The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needle sticks.

The 19Ga. And 22 GA. BNX™ Aspiration Needles are also intended to implant fiducial markers under endoscopic ultrasound to radiographically mark soft tissue for future therapeutic procedures.

SharkCore Fine Needle Biopsy System: The device is used with an ultrasound endoscope for fine needle biopsy (FNB) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract. The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needle sticks.

Technological Characteristics:

The modified BNX FNA / SharkCore FNB Systems are similar to the legally marketed devices described in K142198 and K141894 respectively in terms of principle of operation, technological and performance characteristics (control mechanism, environmental specifications, dimensional specifications, ergonomics of patient-user interface, packaging, sterilization and shelf life), materials, anatomical site, operating instructions, and single-use disposition.

Performance Data:

Bench testing has been performed for those attributes that may be impacted by the modifications made to the subject devices which demonstrates that the proposed modified BNX FNA / SharkCore FNB Systems met the required specifications for completed design verifications tests which included evaluation of unlocking forces, retention forces, sheath extension over the needle, dimensional specifications, bond strengths and durability.

Conclusion:

The results of the non-clinical testing and a comparison of similarities and differences between the modified devices and the respective predicate devices demonstrate that the proposed and predicate devices are substantially equivalent.
