

kubtec

KO 71233

JUN 20 2007

510 (k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

4/30/07

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Joseph Azary on behalf of KUB Technologies, Inc.

Contact:

Joseph Azary
543 Long Hill Avenue
Shelton, CT 06484
Tel: (203) 944-9320
Fax: (203) 944-9317.

Manufacturer:

KUB Technologies, Inc.
1317 Mill Plain Road, Unit A
Fairfield, CT 06824
FDA Establishment Registration# Pending

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are:

- XPERT Specimen Radiography System
- XPERT 40

Specimen X-Ray System / Cabinet

Class II, Product Code MWP, 21 CFR 892.1680

Predicate Device [21 CFR 807.92(a)(3)]

- piXarray by Biotics - K052433
- Dx-50 by Faxitron – K061361
- MX 20 by Faxitron – K953404 (the product formerly owned by Micro Focus Imaging)

Description of the Device [21 CFR 807.92(a)(4)]

The XPERT Specimen Radiography System is a self contained, shielded cabinet x-ray system designed to meet imaging requirements for surgically excised and needle core biopsies. This device does not expose the patient to radiation, it is used for biopsy tissue samples only. This equipment provides high resolution, high contrast, X-ray images, using either radiographic film up to 10x12” or digitally with the DICOM compliant DIGIVIEW digital detectors up to 8x10” in size.

With its small focal spot x-ray source and adjustable sample positioning capability, the XPERT 40 provides variable magnification for increased visibility and sharpness of detail for lesions and abnormalities in biopsies.

The device is provided with a PC including the DICOM compliant software and an LCD monitor for high resolution imaging.

Intended Use [21 CFR 807.92(a)(5)]

Provide digital x-ray images of harvested tissue specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

Technological Characteristics [21 CFR 807.92(a)(6)]

The device is substantially equivalent to the predicate device based on a comparison on physical and performance characteristics.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed electrical and radiation safety requirements, as well software validation testing.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

KUB Technologies, Inc.
% Mr. Joseph M. Azary
Official Correspondent
Azary Technologies, LLC
543 Long Hill Avenue
SHELTON CT 06484

Re: K071233

Trade/Device Name: Kubtec XPERT 40
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MWP
Dated: April 30, 2007
Received: May 3, 2007

JUN 20 2007

Dear Mr. Azary:

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.



Protecting and Promoting Public Health

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.

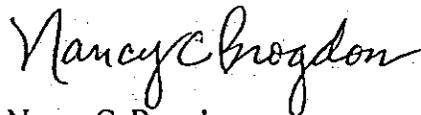
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K071233

Device Name: Kubtec XPERT 40

Indications For Use:

Provide digital x-ray images of harvested tissue specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure.

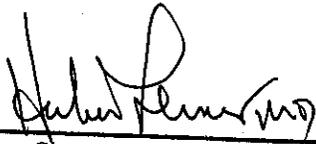
Prescription Use X
(Part 21 CFR 801 Subpart D)

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 Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K071233

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