K101832

AUG 27 2010

Section 5 – 510(k) Summary

Date Prepared:	June 30, 2010
Company:	Angiotech 3600 S.W. 47th Ave., Gainesville, FL 32608
Contact:	Trudy D. Estridge, Ph.D. Vice President, Regulatory Affairs Angiotech 1618 Station Street Vancouver, British Columbia Canada V6A 1B6 Voice: 604-221-6916 Fax: 703-673-0061 Email: testridge@angio.com
Device trade name:	BioPince™ Ultra Full Core Biopsy Instrument
Device Common Name:	Instrument, Biopsy
Device classification:	Instrument, Biopsy Product code KNW 21 CFR 876.1075 Class II
Legally marketed devices to which the device is substantially equivalent:	K904987 BioPince™ Full Core Biopsy Instrument K982960 Tru•Core™ Disposable Automatic Biopsy Instrument K042464 V-Core™ Full Core Breast Biopsy Instrument K050120 Easy Core™ Biopsy System
Description of the device:	The BioPince™ Ultra Full Core Biopsy Instrument is an automatic, disposable biopsy instrument that cuts a full core specimen of soft tissue. The instrument is designed to expel the specimen upon re-cocking of the instrument which prepares the instrument for taking another sample (i.e., ready to be fired). The instrument has two firing trigger buttons with an indicator window and safety button. The instrument is available in 14G, 16G, 18G and 20G needle sizes and 10cm, 15cm and 20cm lengths.

Indications for Use: The automatic BioPince™ Ultra Full Core Biopsy Instrument is intended for multiple percutaneous full-core sampling of soft tissue, tumors, or masses for histological analysis. Soft tissue sampling includes, but is not limited to, kidney, liver, breast, prostate and various soft tissue lesions.

Substantial Equivalence: The BioPince™ Ultra Full Core Biopsy Instrument has the same intended use as the BioPince™ Full Core Biopsy Instrument and the Easy Core™ Biopsy System, and the same size ranges as the Tru•Core™ Disposable Automatic Biopsy Instrument. The BioPince™ Ultra Full Core Biopsy Instrument has an equivalent cutting mechanism as the V-Core™ Instrument. The BioPince™ Ultra Full Core Biopsy Instrument has the same technological characteristics in terms of design and materials as its predicates.

Performance tests: Performance testing confirms that the BioPince™ Ultra Full Core Biopsy Instrument is equivalent to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Angiotech
% Trudy D. Estridge, Ph.D.
Vice President, Regulatory Affairs
1618 Station Street
Vancouver, British Columbia
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Re: K101832
Trade/Device Name: BioPince™ Ultra Full Core Biopsy Instrument
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: June 30, 2010
Received: July 01, 2010

Dear Dr. Estridge:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Dep Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510k number if known: K101832

Device Name: BioPince™ Ultra Full Core Biopsy Instrument

Indications for Use:

The automatic BioPince™ Ultra Full Core Biopsy Instrument is intended for multiple percutaneous full-core sampling of soft tissue, tumors, or masses for histological analysis. Soft tissue sampling includes, but is not limited to, kidney, liver, breast, prostate and various soft tissue lesions.

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)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101832