K090611

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March 4, 2009

Contact Information
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Company Information
Inrad, Inc
4375 Donker Court SE
Kentwood, MI 49512
Phone: 616-301-7800
Fax: 616-301-7799

Device Name(s)
Revolution™ Full Core Biopsy Device
Revolution™ Full Core Biopsy Device w/HiLiter®

Device Summary

Trade or Proprietary Name:	Revolution™ Full Core Biopsy Device Revolution™ Full Core Biopsy Device w/HiLiter®
Common or Usual Name:	Biopsy Instrument
Classification Name:	Gastroenterology-urology biopsy instrument (21 CFR 876.1075, Product code KNW)

Name of Predicate(s) or Legally Marketed Device(s)
K904987 – Vibronics Auto Core Biopsy Device
Also known as:
- BioPince® Full Core Biopsy Instrument (currently sold by InterV/Angiotech)
- Inrad Express™ Core Biopsy Device (formerly manufactured for Inrad by Amedic)

K090611

Device Description

The Revolution™ Full Core Biopsy Device is a sterile, disposable device which features a stainless steel cutting cannula with spoon, rotating coring cannula and stylet. The device is comprised of a plastic housing that contains the mechanically actuated components. The key performance attribute of the Revolution™ Full Core Biopsy Device is the capability of obtaining a full core specimen. A variable throw feature allows the user to choose a throw setting ranging from 10 to 25 mm.

Indications for Use

The device is intended for use in obtaining biopsies from soft tissues such as liver, breast, kidney, prostate, spleen, lymph nodes and various soft tissue tumors.

Substantial Equivalence

The Revolution™ Full Core Biopsy Device has the same intended use as the BioPince® Full Core Biopsy Instrument. The device and the predicate device have the same technological characteristics in terms of design and materials.

Performance Testing Summary

Performance testing confirms that the quality of samples obtained with the Revolution™ Full Core Biopsy Device is equivalent to that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2009

Ms. Melissa Lalomia
Director of RA/QA
Inrad, Inc.
4375 Donker Court SE
KENTWOOD MI 49512

Re: K090611
Trade/Device Name: Revolution™ Full Core Biopsy Device and
Revolution™ Full Core Biopsy Device w/HiLiter®
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: March 4, 2009
Received: March 6, 2009

Dear Ms. Lalomia:

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 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.

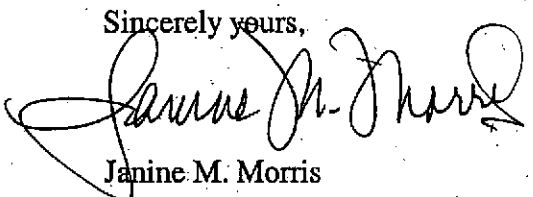
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.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). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,



Janine M. Morris
Acting 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): K090611

Device Name: Revolution™ Full Core Biopsy Device
Revolution™ Full Core Biopsy Device w/HiLiter®

Indications for Use: The device is intended for use in obtaining biopsies from soft tissues such as liver, breast, kidney, prostate, spleen, lymph nodes and various soft tissue tumors.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090611