

K093399

SECTION 5: 510(k) SUMMARY



NOV 19 2009

November 12, 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)**

PreciseCore™ Biopsy Device

**Device Summary**

Trade or Proprietary Name: PreciseCore™ Biopsy Device  
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)**

K994272 – Promex Automated Core Biopsy Device

Also known as:

- SABD™ Disposable Core Biopsy System(US Biopsy is a division of Promex Technologies)
- Inrad® AccuCore Single Action Core Biopsy Device (manufactured for Inrad by US Biopsy)

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### **Device Description**

The PreciseCore™ Biopsy Device is a sterile, disposable device which features a stainless steel cutting cannula and stylet. The device is comprised of a plastic housing that contains the mechanically actuated components. The stylet of the device is stationary, therefore acquiring tissue without an advancement of the needle set beyond the visualized tip.

### **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. For breast biopsy this product is for diagnosis only – not for therapeutic use.

### **Substantial Equivalence**

The PreciseCore™ Biopsy Device has the same intended use as the Inrad® AccuCore Single Action Core Biopsy Device and US Biopsy SABD. The device and the predicate devices 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 PreciseCore™ Biopsy Device is equivalent to that of the predicate device.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Inrad, Inc.  
% Ms. Melissa Lalomia  
Director of Quality and  
Regulatory Affairs  
4375 Donker Court SE  
Kentwood, Michigan 49512

NOV 19 2009

Re: K093399  
Trade/Device Name: PreciseCore™ Biopsy Device  
Regulation Number: 21 CFR 876.1075  
Regulation Name: Gastroenterology-urology biopsy instrument  
Regulatory Class: Class II  
Product Code: KNW  
Dated: October 28, 2009  
Received: November 2, 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.

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

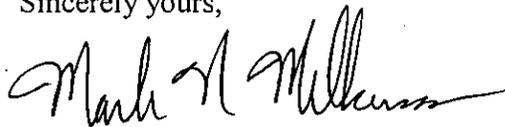
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and 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/cdrh/mdr/> 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/cdrh/industry/support/index.html>.

Sincerely yours,



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

### Indications for Use

510(k) Number (if known): K093399

Device Name: PreciseCore™ Biopsy Device

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. For breast biopsy this product is for diagnosis only – not for therapeutic use.

Prescription Use    
 (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)

*Neil R. Oyle* for *rxm*  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K093399