FEB 4 2000

K993785

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (per 21 CFR 807.92(c))

1. SUBMITTER:

Joseph M. Mazurek
Director of Regulatory Affairs and Quality Assurance
Inrad, Inc.
3956 44th Street S.E.
Kentwood, Michigan 49512
Telephone: (616) 554-7750
Fax: (616) 554-7751
Date Prepared: November 5, 1999

2. PRODUCT NAME:

Proprietary Name: UltraClip Tissue Marker

Common/Usual Name: UltraClip Tissue Marker

Classification Name: Staple, Implantable

3. PREDICATE DEVICE:

Micromark Clip (K970817)
Biopsys Medical, Inc.
3 Morgan
Irving, CA 92718

4. DESCRIPTION OF THE DEVICE:

A sterile, single patient use device comprised of a disposable introducer and applier in addition to the marker itself. The set includes an introducer needle comprised of a plastic molded hub, a needle with 1 cm depth marks, and an ultrasound enhancement on the distal end to aid in needle placement. The applier consists of a stainless steel rod with plastic hub, and the marker, located at the distal end of the introducer needle, is made of stainless steel or . titanium. A plastic safety connector holds the applier and introducer needle in the appropriate position and helps prevent premature deployment of the marker.

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5. **INTENDED USE OF THE DEVICE:**

The UltraClip Tissue Marker is intended for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.

6. **TECHNICAL CHARACTERISTICS COMPARISON TO PREDICATE DEVICE:**

A comparison of features between the Inrad UltraClip Tissue Marker and the Biopsys Medical Micromark Clip is provided in Tab 7. Both devices place a radiographically visible marker in breast tissue to identify the location of biopsy procedure and are technically equivalent.

7. **NON-CLINICAL PERFORMANCE DATA ASSESSMENT:**

Comparison of non-clinical performance data between the Inrad UltraClip Tissue Marker and the Biopsys Medical Micromark Clip indicates the devices are substantially equivalent.

8. **CONCLUSIONS:**

There are no substantial differences between the Inrad UltraClip Tissue Marker and the predicate device. The UltraClip Tissue Marker will utilize a small gauge needle which will result in less trauma to the patient. Other performance characteristics are substantially equivalent.

INRAD, Inc. 3956 44th Street, S.E. Kentwood, Michigan 49512
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

Joseph M. Mazurek, M.S., J.D., RAC
Directory of Regulatory Affairs and Quality Assurance
Inrad, Inc.
3956 44th Street, S.E.
Kentwood, Michigan 49512

Re: K993785
Trade Name: UltraClip Tissue Marker
Regulatory Class: II
Product Code: GDW, FZP
Dated: November 5, 1999
Received: November 8, 1999

Dear Mr. Mazurek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III for
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K993785

510(k) Number (if known):

DEVICE NAME: **UltraClip Tissue Marker**

INDICATIONS FOR USE: **The UltraClip Tissue Marker is intended for use to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.**

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter-Use** _____
(per 21CFR 801.109) **(Optional Format 1-2-96)**

MAO for JZD
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993785