JUL 28 1998

K981721

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92(c))

1. **INDICATIONS:** The indications or intended use for the Inrad Co-axial Introducer Needle as well as the predicate device, Manan Medical Products, Inc. Co-axial Introducer Needle (K 940024) are the same. Both have the same indications, which is to guide biopsy needles to the target lesion for obtaining multiple biopsy samples.

2. **DESIGN**: The design of the Inrad Co-axial Introducer Needle as well as the predicate device, Manan Medical Products is referenced in the Comparison Information Section. The products are identically manufactured using the same manufacturing systems, design and materials. Both needles are manufactured by Manan Medical Products, Inc. The primary differences are packaging and sterilization which will be performed by Inrad.

3. **MATERIALS:** The device is manufactured from plastic and stainless steel. The plastic hubs have no direct patient contact. The stainless steel is the only part of the device that has patient contact. Both products are identically manufactured by Manan Medical Products Inc. using the same manufacturing systems, design and materials

4. **SAFETY AND EFFECTIVENESS:** Manan Medical Products Inc. has sold the identical device in the market place since 1994 and has proven it to be safe and effective. The products are identically manufactured using the same manufacturing systems, design and materials and there are no differences in safety and effectiveness.

5. **DIFFERENCES:** There are no differences between the Inrad Inc. Co-axial Introducer Needle and the Manan Medical Products Inc. Co-axial Introducer Needle other than the source of packaging and sterilization. Inrad will be purchasing the identical product marketed by Manan, bulk and non-sterile, and then packaging and sterilizing the product using Inrad traditional systems.

Anne Armstrong

Anne Armstrong
Director Quality Assurance/Regulatory Affairs

Inrad Incorporated
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Kentwood,MI 49512

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 1998

Ms. Anne Armstrong
Director, Quality Assurance/Regulatory Affairs
INRAD, Inc.
3956 44th Street, S.E
Kentwood, Michigan 49512

Re: K981721
Trade Name: Co-Axial Introducer Needle
Regulatory Class: II
Product Code: KNW
Dated: May 14, 1998
Received: May15, 1998

Dear Ms. Armstrong:

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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (IF Known): K981721

Device Name: **Co-axial Introducer Needle**
Catalog Codes: 611410, 611416, 611810, 611816

Indications for Use: **The device is used to guide a biopsy needle to the target lesion for obtaining multiple biopsy samples.**

(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 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981721