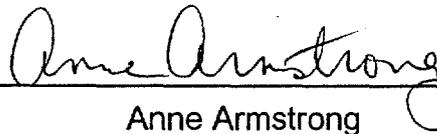


**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS  
(As required by 21 CFR 807.92(c))**

1. **INDICATIONS:** The indications or intended use for the Inrad IV Decanter - Flexible as well as the predicate device, Medtronic/DLP "IV Decanter" (K812852) are the same. Both have the same indications, which is for dispensing fluids from flexible containers.
2. **DESIGN:** The design of the Inrad IV Decanter - Flexible is similar to the predicate device referenced in the Comparison Information Section. It features a flexible tube with a spike attached at one end for attaching to the flexible bag. A clamp is furnished as a means of stopping the fluid flow from the bag which is the same as the Medtronic/DLP "IV Decanter".
3. **MATERIALS:** The device is manufactured from plastic which has no patient contact. The device has been tested for biocompatibility based on these conditions.
4. **SAFETY AND EFFECTIVENESS:** There are no differences in safety and effectiveness. The materials have undergone acceptable biocompatibility testing. The intended use is the same as Medtronic/DLP "IV Decanter" predicate product. Design characteristics are similar to the Medtronic/DLP "IV Decanter" predicate product.
5. **DIFFERENCES:** Primary difference between the Inrad "IV Decanter" and Medtronic/DLP "IV Decanter" is the color of the tubing which is used to distinguish the two products from one another.



Anne Armstrong  
Director Quality Assurance/Regulatory Affairs

Inrad Incorporated  
3956 44th St. SE  
Kentwood, MI 49512

Phone: (616) 554-7750 Ext. 102  
Fax: (616) 554-7751



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 17 1998

Ms. Anne Armstrong  
Director Quality Assurance and Regulatory Affairs  
Inrad Incorporated  
3956 44<sup>th</sup> Street S.E.  
Kentwood, Michigan 49512

Re: K980587  
Trade Name: IV Decanter-Flexible  
Regulatory Class: II  
Product Code: LHI  
Dated: February 13, 1998  
Received: February 17, 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

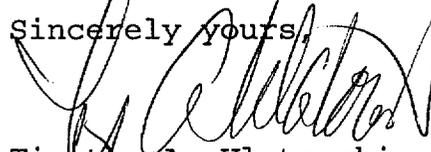
Page 2 - Ms. Armstrong

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) 594-4692. 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,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K980587/A1

510 (k) Number (IF Known): **K980587**

Device Name: **#40050 IV DECANTER- FLEXIBLE**

Indications for Use: **Aseptic Decanting of fluids from flexible containers**

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FDA/CDRH/ODE/DNC

**(Please Do Not Write Below This Line - Continue on Another Page If Needed)**

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

*Patricia Ciccone*

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K980587

SK-11