



K965112

SUMMARY OF SAFETY AND EFFECTIVENESS

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060
Registration #: 1417592
Phone: (847) 949-2639
Fax: (847) 949-2643
Lara N. Simmons
Corporate Regulatory Affairs Manager

OCT 10 1997

December 18, 1996

DEVICE NAME: Catheterization Laboratory Trays/Kits/Packs
PROPRIETARY NAME: Medline Catheterization Laboratory Trays/Kits/Packs
COMMON NAME: Catheterization Laboratory Trays/Kits/Packs
PERFORMANCE STANDARDS: None per Section 514.

CLASSIFICATION NAME:

We have been unable to locate specific classifications for these devices. The contents of each tray are either Class I or Class II medical devices, drugs or non-medical materials (i.e. packaging, cartons and labels).

PRODUCT SPECIFICATIONS

Medline Catheterization Laboratory Trays/Kits/Packs are an assemblage of medical materials to be used by medical professionals during cardiac catheterization, angiography, or arteriogram procedures. These procedures may include actual catheterization, implantation of pacemakers, or other procedures that are specific to the Catheterization Laboratory. The trays will be assembled using Medline and other manufacturer's materials, medical devices and/or drugs.

The devices are custom to our customers who specify the contents, quantity and placement of the individual items in the tray, kit, or pack. Attached is a list of individual components that are likely to be in any of these devices. These items are standard for catheterization laboratory procedures and we expect that only quantities will change from one tray to another. The customer may also specify a specific brand of similar items or minor variations of items.

Medline intends to assemble these kits in a class 10,000 clean room or controlled environment and to sterilize using either EtO or gamma radiation at a contracted sterilization facility.

INTENDED USE/INDICATIONS FOR USE

Medline Catheterization Laboratory Trays/Kits/Packs are intended for use by licensed physicians. The intended use of the medical products assembled in these kits will not be changed from the manufacturer's original intended use.

SUMMARY - CONTINUED

SUBSTANTIAL EQUIVALENCE

We certify that components or individual items of the assembled device have been on the market prior to May 28, 1976, or have been shown by their manufacturer to be substantially equivalent to pre-amendment devices, or to be exempt from 510(k) notification requirements.

The component list attached as Exhibit A includes the name and regulatory status of the intended components used in these trays. We do not expect this list to change, however, if additional components and/or manufacturers must be added, we will certify the regulatory compliance of the added devices, and keep the information in our Master Device Record.

Many companies assemble various medical devices into a kit or tray for specific medical procedures. Similar procedure specific kits are in commercial distribution and are marketed by Baxter Healthcare, located in Waukegan, Illinois, and Sterile Concepts located in Richmond, VA. We are unable to locate 510(k)s for this category of kits for either manufacturer, however, Medline Industries, Inc. has approved 510(k)'s for similar kits under K962826.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms •Lara N. Simmons
Corporate Regulatory Affairs Manager
Medline Industries, Inc.
One Medline Place
Mundelein, Illinois 60060-4486

OCT 10 1997

Re: K965112
Catheterization Laboratory Trays/Kits/Packs
Regulatory Class: II
Product Code: DQO
Dated: June 24, 1997
Received: June 15, 1997

Dear Ms. Simmons:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the trays, kits and packs have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray/pack. 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 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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used for the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.
2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

In addition, we have determined that your device kit contains components (see highlighted items on the attached lists) which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the

Page 3 - Ms. Lara N. Simmons

drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

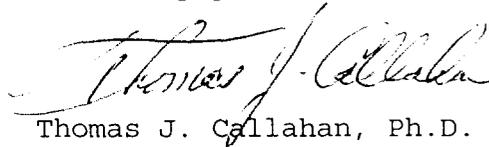
Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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,



Thomas J. Callahan, Ph.D.
Director

Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INTENDED USE

Page 1 of 1

510(k) Number (if known): (N/A)

Device Name: Medline Catheterization Laboratory Trays/Kits/Packs

Indications for Use:

Medline Catheterization Laboratory Trays/Kits/Packs are intended for use by licensed physicians. The intended use of the medical products assembled in these kits will not be changed from the manufacturer's original intended use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

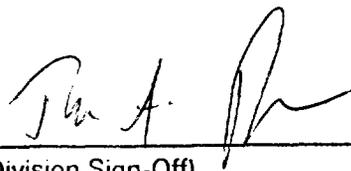
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K965112