



K971208

Medline Industries, Inc.

One Medline Place
Mundelein, Illinois 60060.4486

1.847.949.3109
1.800.950.0128
Fax 1.847.949.2643

13

Corporate Quality Assurance/Regulatory Affairs

SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 13 1997

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

March 31, 1997

DEVICE NAME: Orthopedic Trays/Kits/Packs
PROPRIETARY NAME: Medline Orthopedic Trays/Kits/Packs
COMMON NAME: Orthopedic 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 Orthopedic Trays/Kits/Packs are an assemblage of medical materials to be used by medical professionals during orthopedic procedures such as total hip replacement, upper or lower extremity surgery, podiatry, and total knee replacement procedures. These packs may be produced for other procedures that are considered orthopedic surgery. 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 Orthopedic 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 Orthopedic 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.

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 .
[REDACTED]

We are unable to locate 510(k)s for this category of kits for Baxter.