



Medline Industries, Inc.

One Medline Place
Mundelein, Illinois 60060.4486

1.847.949.3109
1.800.950.0128
Fax 1.847.949.2643

Corporate Quality Assurance/Regulatory Affairs

SUMMARY OF SAFETY AND EFFECTIVENESS

K970282

P192

January 22, 1997

MAR - 6 1997

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060
Registration #: 1417592
Phone: (847) 949-5500 x1131
Fax: (847) 949-2643
Christine M. Galea
Corporate Regulatory Affairs

DEVICE NAME: Circumcision Trays
PROPRIETARY NAME: Medline Circumcision Trays
COMMON NAME: Circumcision Trays
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 Circumcision Trays are an assemblage of medical materials to be used by medical professionals during circumcision procedures. 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. 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 Circumcision Trays 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.



Medline Industries, Inc.

One Medline Place
Mundelein, Illinois 60060.4486

1.847.949.3109
1.800.950.0128
Fax 1.847.949.2643

Corporate Quality Assurance/Regulatory Affairs

SUMMARY OF SAFETY AND EFFECTIVENESS (cont.)

K970282
p292

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, such as K884290, Baxter Disposable Circumcision Tray, are in commercial distribution and are marketed by Baxter Healthcare, located in Waukegan, Illinois.