

DEC 07 2001

510(k) Summary
for

K993535

Riley Medical, Inc. MetaPak Multi-Purpose Instrument Tray

1. SPONSOR

Riley Medical, Inc.
27 Wrights Landing
Auburn, ME 04210

Contact Person: Mr. Martin M. Moore
Telephone: 207-786-2775

Date Prepared: November 28, 2001

2. DEVICE NAME

Proprietary Name: Riley Medical, Inc. MetaPak Multi-Purpose Instrument
Tray
Common/Usual Name: Instrument sterilization tray
Classification Name: Accessory to sterilization wrap

3. PREDICATE DEVICES

- Riley MultiPak Surgical Instrument Tray
- Sklar Instruments Instrument Tray

4. DEVICE DESCRIPTION

The Riley Medical MetaPak Multi-Purpose Instrument Tray (MetaPak Instrument Tray) is an instrument container consisting of a rectangular box base with a cover that fastens to the base using latches on the short ends. The following sizes of bases and lids are available:

- Tall base and lid: 22" x 10" x 6"
- Short base and lid: 22" x 10" x 4"
- Extra long base and lid: 26" x 10" x 6"

Insert trays can be stacked in the container base to increase the instrument-carrying capacity of the container. The following insert sizes are available:

- Full insert: 21" x 9.5" x 2.5"
- Small insert: 10" x 9.5" x 2.5"

Protective mats are available that can be placed on the insert trays and in the bottom of the container base to stabilize and protect the instruments. Slotted instrument bars and holders are also available to organize, stabilize, and protect the instruments in the container.

5. INTENDED USE

The MetaPak Instrument Tray is used for loading surgical instruments in order to conveniently organize, sterilize, transport, and store the instruments between uses.

The MetaPak Instrument Tray can be used in pre-vacuum steam and ethylene oxide sterilization cycles.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed MetaPak Instrument Tray and the predicate MultiPak and Sklar Instrument Trays are all used for storage, transport, and sterilization of surgical instruments between uses. Both the proposed and predicate devices are suitable for use in pre-vacuum steam and ethylene oxide sterilization processes.

The MetaPak Instrument Tray is identical to the predicate MultiPak Instrument Tray, cleared for marketing as K944025, with the exception of a modification to the materials for the container base. The original MultiPak Instrument Tray container base was constructed entirely of Radel plastic. The MetaPak Instrument Tray container base will be offered in aluminum, stainless steel, and an aluminum/Radel combination with the long sides made of aluminum and short sides made of Radel plastic.

7. PERFORMANCE TESTING

Validation testing was conducted which confirmed that sterilization conditions were achieved in fully loaded MetaPak Instrument Trays of all three container base material compositions containing one full insert and two half inserts, protective mats, and accessories in pre-vacuum steam and ethylene oxide sterilization processes.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 07 2001

Riley Medical, Incorporated
C/O Ms. Mary McNamara-Cullinane
Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K993535

Trade/Device Name: Metapak Multi-Purpose Instrument Tray
Regulation Number: 880.6850
Regulation Name: Instrument Sterilization Tray
Regulatory Class: II
Product Code: FRG
Dated: October 9, 2001
Received: October 10, 2001

Dear Ms. Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

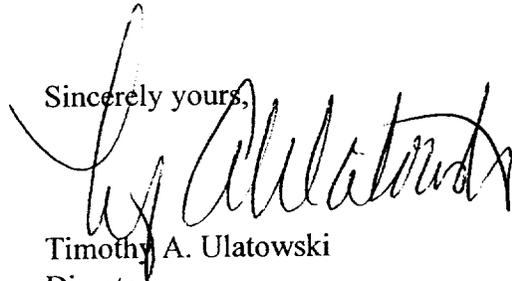
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/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

510(k) Number (if known): K993535

Device Name: Riley Medical MetaPak Multi-Purpose Instrument Tray

Indications For Use:

The Riley Medical MetaPak Multi-Purpose Instrument Tray is used for loading surgical instruments in order to conveniently organize, sterilize, transport, and store the instruments between uses.

The Riley Medical MetaPak Multi-Purpose Instrument Tray can be used in pre-vacuum steam and ethylene oxide sterilization cycles.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lim

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

510(k) Number K 99 3535

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Riley Medical, Inc.
Additional Information for K993535

November 28, 2001