

OCT 29 2003

510(k) Summary Pursuant to 21 CFR 807.92

1. Submitted By: Paragon Medical, Inc.
8 Matchett Industrial Park Drive
Pierceton, IN 46562
2. Contact: Cory D. Colman
Paragon Medical, Inc.
8 Matchett Industrial Park Drive
Pierceton, IN 46562
(574) 594-2140
3. Product: Paragon Medical Surgical Instrument
Delivery System
CFR Section 880.6850 Sterilization Wrap
Class II
Pack, Sterilization Wrapper, Bag and
Accessories
Product Code 80 KCT

Description:

Paragon Medical Surgical Instrument Delivery Systems consist of various sizes of metal, plastic, and combination cases and trays with removable lids. The devices are intended to hold and protect medical instrumentation or devices during steam sterilization processes and subsequent storage and transportation. The products are constructed of durable materials and designed with perforations or slots to allow for steam penetration. They are to be used with an appropriate sterilization wrap.

Intended Use:

The Paragon Medical Surgical Instrument Delivery System is intended to hold and protect medical instrumentation during sterilization processes and subsequent storage.

Technological Characteristics and Substantial Equivalence:

The Paragon Devices are primarily constructed of machined, formed, or molded plastic and metal and do not feature any new technological characteristics or materials.

The Paragon Medical, Surgical Instrument Delivery System is comparable in design to that of the PolyVac Surgical Instrument Delivery System manufactured by Symmetry Medical, Inc. (# K102105), and that of MetaPak Multi Purpose Instrument Tray, manufactured by Riley Medical, Inc. (# K993535)

Performance Testing:

The Surgical Instrument Delivery System has been validated to perform effectively during steam sterilization and drying cycles. Various sizes of double wrapped Cases and Trays from the System, fully loaded with medical instrumentation including some with lumens(cannulae) of up to 15” in length x 0.093 dia. have been demonstrated to be effectively sterilized using bioindicators and thermocouples in a 132° C Prevacuum 4 minute cycle. Drying time is from 20-40 minutes.

Conclusions:

The Paragon Medical, Surgical Instrument Delivery System is substantially equivalent to similar devices existing in the market in materials of construction, dimensions, and performance characteristics. It has been shown to be an effective design and when used according to instructions for use, is a useful and valuable device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Cory D. Colman
Executive Vice President, Business Development
Paragon Medical, Incorporated
8 Matchett Industrial Park Drive
Pierceton, Indiana 46562

Re: K032119

Trade/Device Name: Paragon Medical Surgical Instrument Delivery System
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: September 12, 2003
Received: September 16, 2003

Dear Mr. Colman:

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.

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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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number:

K032119

Device Name:

Paragon Medical Surgical Instrument Delivery System

Intended Use:

Paragon Medical's Surgical Instrument Delivery Systems are containment devices for medical device sterilization. The Systems are constructed of metal and/or plastic with perforations to facilitate steam penetration. They are to be used with an approved sterilization wrap.

Sterilization Cycle: Prevacuum 132°C for 4 minutes
Dry Time 20-40 minutes

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susanna F. Brown D.

(Division Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032119

Prescription Use _____
(Per CFR 801.109)

or

Over-the-counter Use _____