REVISED 510(k) SUMMARY

JUN 2 3 2011

K110500

MacPherson Medical's Stat-Mat® Minor

Submitter:

MacPherson Medical Inc.

930 Main Street, Suite 202

Acton, MA 01720

Phone: (978) 800-4641

Facsimile: (866) 280-2078

Contact Person: Brad MacPherson

Date Prepared: June 21, 2011

Device Name:

Stat-Mat® Minor

Sponsor:

MacPherson Medical Inc.

930 Main Street, Suite 202

Acton, MA 01720

Common or Usual Name

Sterilization Tray

Classification Name

Accessory to sterilization wrap

Predicate Devices

PolyVac's Surgical Instrument Delivery Systems (K012105)

Riley Medical, Inc.'s MetaPak Multi-Purpose Instrument Tray (K993535)

Device Description

The Stat-Mat® Minor is a multipurpose surgical instrument tray that consists of three primary components: a base, cover, and instrument roll. The base and cover are composed of Radel plastic, which meets the requirements for biocompatibility pursuant to ISO-10993 and is compatible with standard steam sterilization methods. The instrument roll is composed of aluminum and is used to keep ringed instruments open during sterilization. The Stat-Mat® does not contact the patient.

Intended Use / Indications for Use

The Stat-Mat® Minor multipurpose surgical instrument tray is used for loading an entire kit of surgical instruments for a specific case in order to conveniently organize, sterilize, transport and store the instruments between uses.

The Stat-Mat® Minor is designed using plastic and metal materials that can be reused with pre-vacuum or gravity displacement steam sterilization methods. The Stat-Mat® Minor should be used only with FDA-cleared and legally marketed sterilization wraps that have been cleared for the sterilization cycles listed below. The Stat-Mat® Minor has been validated with the Dextex II Sterilization Wrap [K800123]. The base containing organized surgical instrumentation can be placed directly on the back table or onto a Mayo Tray. Instruments with lumens were not tested in the Stat-Mat® Minor validation process and are therefore not recommended for use with the Stat-Mat® Minor.

Sterilization cycle parameters

Cycle Type	Temperature	Sterilization Time	Pre-Vac Pulses	Dry Time
Gravity	250°F (121°C)	30 minutes	none	30 minutes
Pre-vacuum	270°F (132°C)	4 minutes	4	30 minutes

Technological Characteristics

The Stat-Mat® Minor includes a quick release cover and ringed instrument separator. The Stat-Mat® Minor can be wrapped in CSR wrap with no sharp edges. It is made of durable materials that are appropriate for holding general surgical instruments and withstanding standard steam sterilization methods. It has ample holes to allow steam to circulate for sterilization.

Performance Data (Nonclinical Testing)

The company conducted testing to validate gravity displacement and pre-vacuum steam sterilization of the Stat-Mat® Minor. 10^6 Geobacillus stearothermophilus spore strips and thermocouples were placed in the test articles. The test articles were double-wrapped in a cleared sterilization wrap and placed in the sterilization chamber. The test articles were successfully sterilized in a pre-vacuum cycle at 132° for a 2-minute half-cycle and a gravity

displacement cycle at 121° for a 15-minute half-cycle. The Stat-Mat® Minor was successfully sterilized for three consecutive and separate sterilization half cycles. The cycle conditions were considered adequate to achieve a sterility assurance level of 10^{-6} at twice the stated exposure time. The thermocouples passed the verification calibration, and all positive and negative controls were satisfactory.

Conclusion: The results of the sterilization validation testing performed demonstrate that the Stat-Mat® Minor is as safe, as effective, and performs as well as the predicate devices.

Substantial Equivalence

The Stat-Mat® Minor is as safe and effective as Polyvac's Surgical Instrument Delivery Systems or Riley Medical, Inc.'s MetaPak Multi-purpose Instrument Tray. The Stat-Mat® Minor has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Stat-Mat® Minor and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Stat-Mat® Minor is as safe and effective as Polyvac's Surgical Instrument Delivery Systems or Riley Medical, Inc.'s MetaPak Multi-purpose Instrument Tray. Thus, the Stat-Mat® Minor is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MacPherson Medical, Incorporated
C/O Mr. Howard Holstein
Hogan Lovells US, LLP
Columbia Square
555 13th Street, NW
Washington, D.C. 20004

JUN 23 2011

Re: K110500
Trade/Device Name: Stat-Mat® Minor
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: June 16, 2011
Received: June 16, 2011

Dear Mr. Holstein:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

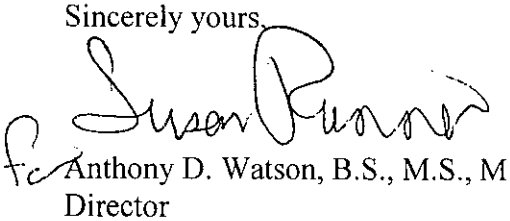
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Anthony D. Watson, B.S., M.S., M.B.A.
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 (if known): K 110500

Device Name: Stat-Mat® Minor

Indications for Use:

The Stat-Mat® Minor multipurpose surgical instrument tray is used for loading an entire kit of surgical instruments for a specific case in order to conveniently organize, sterilize, transport and store the instruments between uses.

The Stat-Mat® Minor is designed using plastic and metal materials that can be reused with pre-vacuum or gravity displacement steam sterilization methods. The Stat-Mat® Minor should be used only with FDA-cleared and legally marketed sterilization wraps that have been cleared for the sterilization cycles listed below. The Stat-Mat® Minor has been validated with the Dextex II Sterilization Wrap [K800123]. The base containing organized surgical instrumentation can be placed directly on the back table or onto a Mayo Tray. Instruments with lumens were not tested in the Stat-Mat® Minor validation process and are therefore not recommended for use with the Stat-Mat® Minor.

Sterilization cycle parameters:

Cycle Type	Temperature	Sterilization Time	Pre-Vac Pulses	Dry Time
Gravity	250°F (121°C)	30 minutes	none	30 minutes
Pre-vacuum	270°F (132°C)	4 minutes	4	30 minutes

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Williams

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

510(k) Number: K110500