

11082988

FEB 13 2009

## **Medivators Advantage Plus Endoscope Reprocessing System and Rapicide PA High Level Disinfectant**

### 510(k) Summary of Safety and Effectiveness

Manufacturer: Medivators Reprocessing Systems, a Division of Minntech Corporation  
Address: 14605 28<sup>th</sup> Avenue North  
Mpls., MN 55447  
USA  
Official Contact: Lynn Lueders  
Director, Regulatory Affairs

Medivators has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalence of the Advantage Plus Endoscope Reprocessing System and Rapicide PA High Level Disinfectant to other endoscope reprocessors and high level disinfectants currently marketed in the U.S.

#### **1. Device Description**

The Advantage Plus AER is an electro-mechanical system intended to test, wash, and high level disinfect flexible fiberoptic and video endoscopes between uses. It is not intended for reprocessing rigid endoscopes. The Advantage is capable of asynchronously reprocessing two scopes at a time.

The Advantage Plus system uses the peracetic acid based Rapicide PA High Level Disinfectant. The Advantage Plus is a single use system in that it mixes the Part A and Part B of the Rapicide PA with water immediately prior to reprocessing and the disinfectant is not reused.

Endoscopes must be pre-cleaned and manually cleaned to SGNA and facility guidelines prior to placing in the system for reprocessing.

After the scopes are connected to the AER, the system tests the endoscopes for blockages in the channels and leaks in the outer skin, and then proceeds to the washing step. The system also includes an optional channel connectivity test to verify proper connection of the fluid channels for reprocessing. If the endoscopes pass the blockage and leak tests and

the washing cycle has been completed, the system proceeds to rinse the instruments and begins the disinfection cycle.

For the disinfection cycle, the incoming water is mixed with the two part germicide in the basin. The temperature of the incoming water is monitored to ensure that water temperature is within the operating constraints (30°C) required for disinfection after the water and germicide are mixed together. Following the 5 minute disinfectant contact time, the user takes a sample to test for MRC and then the disinfectant is emptied from the basin into the drain from the machine. Following disinfection, the endoscopes are rinsed and dried by the machine, either by filtered air or an optional alcohol rinse, and are then removed from the machine for the next use.

The machine has many built in safety features which stop the cycle and alarm when certain conditions exist which could indicate that disinfection might be compromised. These alarms and causes are defined in the directions for use for the product.

The machine also prints records by endoscope serial number indicating the results of testing, disinfection, number of disinfections, etc. which are required for permanent records.

Rapicide PA High Level Disinfectant is a peracetic acid based, two part disinfectant. Part A contains the active ingredients and Part B contains anticorrosive agents and surfactants. Part A and Part B are mixed in the machine and diluted with water. The Minimum Recommended Concentration (MRC) of Rapicide PA is 850 ppm of peracetic acid. A test strip is used to ensure that the use solution is above the MRC.

## **2. Intended Use**

Medivators Advantage Plus Endoscope Reprocessing System tests, washes, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The Advantage Plus system is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes.

Rapicide PA High Level Disinfectant is intended for use with the Advantage Plus Endoscope Reprocessing System to provide high level disinfection of endoscopes when used according to the directions for use.

Rapicide PA Test Strips are used after the disinfection cycle to ensure that the used disinfectant is above the minimum recommended concentration (850ppm peracetic acid); this ensures that the disinfectant was above MRC during the entire disinfection cycle.

Rapicide PA should be used under the following contact conditions:

Claim	Time	Temperature	Minimum Recommended Concentration of Peracetic Acid (MRC)
High Level Disinfection	5 minutes	30(°C)	850ppm

**3. Comparison to Another Device in Commercial Distribution Within the United States**

The Advantage Plus is equivalent in function and indications to the Medivators MDS Endoscope Reprocessing System (K063876) and the Advanced Sterilization Products' EvoTech™ Integrated Endoscope Disinfection System (K061899). All of the machines have the same indications for use and the same methods of providing disinfection.

Rapicide PA High Level Disinfectant is equivalent in indications and usage to Acecide High Level Disinfectant and Sterilant (K041984) and Peract 20 Liquid Sterilant (K960513). All of the products are peracetic acid based germicides labeled for providing high level disinfection to flexible endoscopes.

**4. Summary of Testing**

Medivators has provided testing to show that the Advantage Endoscope Reprocessing system and Rapicide PA are safe and effective for their intended use following the requirements listed in the FDA's Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (dated August 1993) and the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants (January 3, 2000).

The efficacy testing for Rapicide PA is summarized in the table below:

### Efficacy Testing Summary Table

Tests	Organisms	Results
Sporicidal	<i>Clostridium sporogenes</i> and <i>Bacillus subtilis</i> spores	Total Kill
Confirmatory Sporicidal	<i>Clostridium sporogenes</i> and <i>Bacillus subtilis</i> spores	Total Kill
Tuberculocidal	<i>Mycobacterium bovis</i> (BCG)	Total Kill
Virucidal	Polio virus type 2	Complete Inactivation
Virucidal	Herpes simplex virus type 1	Complete Inactivation
Virucidal	Human Immunodeficiency Virus type 1	Complete Inactivation
Fungicidal	<i>Trichophyton mentagrophytes</i>	Total Kill
Use-Dilution	<i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Salmonella</i> <i>choleraesuis</i>	Total Kill
Simulated-Use	<i>Mycobacterium terrae</i>	>6 log Reduction
In-Use	Clinically Used Scopes	Total Kill

#### Material Compatibility

The effect of disinfectant on the materials used in endoscopes and in the AER system was evaluated and showed that the endoscopes and AER materials showed no significant deterioration over time. Studies were also presented to show that the filters used in the water filtration system were compatible with Rapicide PA.

#### Biocompatibility

The amount of disinfectant residue left on endoscopes after the disinfection and rinsing cycles was evaluated and compared to determined safe levels. The results of the testing showed that any remaining residues would not have an effect on patients or users.

Performance Data

Data was provided to the FDA to show that the machine performs as required. This evaluation included testing to show that the leak check, blockage check, connectivity checks, washing cycle, disinfection cycle, rinse cycles, and drying cycles performed correctly. Any error messages were tested to ensure they function properly to notify users of any possible failure modes. Testing was performed to show that all critical parameters of the machine function correctly.

Testing was provided that showed that the disinfectant remained at its required temperature for the length of time required for high level disinfection.

Testing was completed that showed that the Advantage Plus self disinfection cycle works properly by disinfecting all areas of the machine, including the water filtration system.

Studies were performed to show that the water filtration system will function appropriately over time and that the machine will alarm if water filters are plugged to a point which will lower the water pressure below required input. This study also showed that the filters remained bacterial retentive even when plugged to a point that causes the machine to alarm.

**5. Summary of Substantial Equivalence**

Medivators has provided the above information in the form of a 510(k) to support the claim that the Advantage Plus Endoscope Reprocessing System and Rapicide PA are safe and effective when used in accordance with the device labeling.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Medivators Reprocessing Systems  
C/o Ms. Lynn Lueders  
Director, Regulatory Affairs  
Minntech Corporation  
14605 28<sup>th</sup> Avenue North  
Minneapolis, Minnesota 55447-4822

FEB 13 2009

Re: K082988

Trade/Device Name: Medivators Advantage Plus Endoscope Reprocessing System  
and Rapicide PA High Level Disinfectant

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and Accessories

Regulatory Class: II

Product Code: FEB

Dated: January 28, 2009

Received: January 29, 2009

Dear Ms. Lueders:

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.

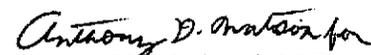
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
Ginette Y. Michaud, M.D.

Acting 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

510(k) Number (if Known):

Device Name: Medivators Advantage Plus Endoscope Reprocessing System and Rapicide PA High Level Disinfectant

Indications for Use:

Medivators Advantage Plus Endoscope Reprocessing System tests, washes, disinfects and rinses flexible endoscopes, such as fiberoptic and video endoscopes between patient uses. The Advantage Plus system is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes. Manual cleaning of endoscopes is required prior to placement in the Advantage Plus system.

Rapicide PA High Level Disinfectant is intended for use with the Advantage Plus Endoscope Reprocessing System to provide high level disinfection of endoscopes when used according to the directions for use. Rapicide PA Test Strips are used after the disinfection cycle to ensure that the used disinfectant is above the minimum recommended concentration (850ppm peracetic acid); this ensures that the disinfectant was above MRC during the entire disinfection cycle. Rapicide PA should be used under the following contact conditions:

Claim	Time	Temperature	Minimum Recommended Concentration of Peracetic Acid (MRC)
High Level Disinfection	5 minutes	30(°C)	850ppm

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*ges for ssm*

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

510(k) Number:           K082988