



# PRODUCT BULLETIN

<b>Distribution:</b>	
International Distributors	✓
International Management	✓
US Clinical Specialists	✓
US Customer Service	✓
US Field Sales	✓
US Technical and Field Service	✓

Date: April 27, 2011

**RE:** This communication was developed to list current 510(k) clearances for Medivators endoscope reprocessors and disinfectants, and provide an explanation of FDA requirements with regards to device changes.

## 510(k) CLEARANCES:

Medivators is the brand name for our product line, while Minntech is the corporation under which 510(k) filings are submitted. When reviewing FDA listings, the company name may be listed as either Medivators or Minntech Corporation.

All reprocessors that we offer for sale have been cleared for use by the FDA and have separate 510(k) clearance numbers. Details relating to 510(k) FDA clearance for all our reprocessor's and disinfectants are outlined below. The number sequence in parentheses beginning with the letter "K" is the number assigned by FDA for every device clearance.

**CER: [#K871712]** The original 510(k) clearance was issued to Machida America, Inc. and the CER was at that time called Machida America Model AC-5000 Automatic Disinfect. Medivators purchased the CER product from Chris Lutz Medical, who had previously acquired the technology from Machida. The FDA is fully aware that Medivators/Minntech now markets this table-top reprocessor.

**ADVANTAGE PLUS: [#K102996]** Original clearance of the Advantage Plus, including Rapticide PA High level Disinfectant occurred on January 28, 2009 under K082988. On January 13, 2011 the Advantage Plus received clearance for the elimination of manual cleaning prior to disinfection in the machine.

**ADVANTAGE MU: [#K063876]** This AER is listed on the FDA website as "MDS for Endoscope Reprocessing". "MDS" was the original name given to the Advantage reprocessor and is the name that is still used throughout Europe. The MDS was subsequently renamed Advantage MU in the US.

**DSD-201: [#K914145]** The DSD-201 is the current name for the previous DSD-91 endoscope reprocessor which was released in 1991. The Medivators DSD-201 is marketed under the original DSD-91 FDA clearance, with the model prefix changing to reflect system updates (released in 2001). The 510(k) clearance for DSD applies to the DSD-201.

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**DSD-EDGE [#K092387]** The DSD EDGE was cleared by FDA as an automated endoscope reprocessor in April 2010 as a new device.

**Rapicide High Level Disinfectant and Sterilant: [#K993042]**

**Rapicide PA High Level Disinfectant: [#K082988]** Rapicide PA was submitted with the original Advantage Plus submissions and was cleared at the same time.

A complete listing of MEDIVATORS reprocessors and disinfectants was prepared and released by ECRI and can be found on the following website.

[https://www.ecri.org/Forms/Pages/STERIS-System-1-\(SS1\)-Replacement.aspx](https://www.ecri.org/Forms/Pages/STERIS-System-1-(SS1)-Replacement.aspx)

In addition, the FDA's searchable 510(k) database can be accessed at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

## **DEVICE CHANGES:**

The FDA allows changes to 510(k) cleared devices as long as those changes are made in accordance with FDA Guidance Documents and are not defined as "substantial". Any change must be documented per FDA Quality System Requirements and must be fully validated. FDA has a published Guidance Document that outlines when it is necessary to file a new 510(k) and when a company can document the changes via what is known as a "letter to file". Substantial changes, that then require a new 510(k) submission, are defined by FDA *"as a change or modification to a device that could **significantly affect the safety or effectiveness of the device or a change or modification in the intended use or claims of a device**"*.

Minntech's Regulatory Affairs group reviews every Minntech Engineering Change Order based on the FDA's Guidance Document, and determines whether the change affects the product's 510(k) clearance.

Examples of some of the differences between the DSD-91 and the DSD-201 are as follows:

- Blue 6 volt indicator lights on the DSD-91 were changed to 28 volt green lights
- PVC manifolds were changed from a machined manifold to a molded manifold
- Manually fabricated disinfectant reservoirs were changed to a molded reservoirs
- The stainless steel internal filter housing was changed to plastic
- The control panel was changed from pressure-switch activation to a tactile, membrane-based activation.

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Each and every change made to the DSD has been reviewed according to the FDA Guidance Document. Every change has been documented, validated and determined to be not substantial. The DSD EDGE was submitted as a new device, since the changes in the device as compared to the DSD-91 and DSD-201 were considered substantial.

For additional information, please contact Medivators Technical Support at 1-800-444-4729.

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