

Davol Inc.
Subsidiary of C. R. Bard, Inc.
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K964211



DEC - 2 1996

Section VI. 510(k) Summary of Safety and Effectiveness (page 1 of 2)

Submitter Information:

Company Name:

Davol Inc
100 Sockanossett Crossroads
Cranston, RI 02920
Phone: 401-463-7000
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Contact: Christine Nichols
Date of Preparation: 10/2/96

Device name:

Trade Name: Davol® Plume Filter (hydrophobic)
Common name: Laparoscopic Plume Filter
Classification name: Laparoscope, General & Plastic Surgery;
Gynecological (and accessories);
Endoscopic tube, smoke removal

Predicate Device Name:

Contain™ Hydrophobic safety filter

Device description:

Hydrophobic multilayered filter with vacuum tubing for attachment to wall vacuum or suction source.

Intended Use

To be connected to suction / vacuum assemblies to filter smoke particulates / aerosols, and retain aqueous fluids generated during laparoscopic electrosurgery or laser surgery.

Technological

Characteristics Summary:

The Davol® Plume Filter proposed in this submission is substantially equivalent to the currently marketed Contain™ Hydrophobic Safety Filter.

The 510(k) "Substantial equivalence decision making process (detailed) decision tree" was utilized to make a determination of substantial equivalence.



(510(k) Summary of Safety and Effectiveness Continued) (page 2 of 2)

1. **Does the new device have the same indication statement?**
YES. Both the Davol Plume filter and the Contain filter are intended to be connected to wall suction or suction assemblies to filter smoke particulates / aerosols and retain aqueous fluids generated during surgical procedures. The filter will retain 99.99% of all particles / aerosols 0.12 microns and greater, and all aqueous fluids up to normal vacuum pressures.

2. **Does the new device have the same technological characteristics, e.g. design, materials, etc?**
YES. The Davol Plume filter is identical in design, function, and materials to the Contain filter currently manufactured and commercialized. A suction/vacuum tube will be provided pre-attached to the Davol Plume filter for user convenience in attaching to a suction/ vacuum source (users of the Contain filter presently have to supply the suction tube).

3. **Are the Descriptive Characteristics precise enough to ensure equivalence?**
YES. The Contain filter is identical to the Davol Plume filter proposed in this 510(k) submission. Therefore, the descriptive characteristics are enough to ensure equivalence.

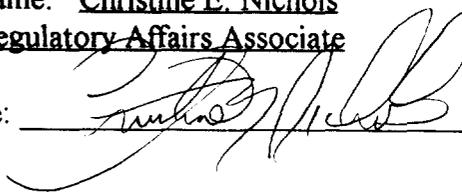
Conclusion:

Based upon the above information, the Davol Plume filter is substantially equivalent to the Contain Hydrophobic safety filter.

Typed Name: Christine E. Nichols

Title: Regulatory Affairs Associate

Signature: _____

 10/21/96