

**Davol<sup>®</sup> Nasogastric Sump Tube  
with PreVent<sup>™</sup> Anti-Reflux Filter  
510(k) Summary**

**JUL 24 1996**

**Predicate Device:** Salem Sump Tube with Anti-Reflux Valve

**Intended Use of the Device:**

The Davol Nasogastric Sump Tube with PreVent Anti-Reflux Filter is intended for gastric decompression, gastric lavage, and administration of nutritional supplements and medication.

**Device Description:**

The Davol Nasogastric Sump Tube with PreVent Anti-Reflux Filter is a dual lumen device used for gastric decompression (removal of gastric secretions and gases), gastric lavage, and administration of nutritional supplements and medication. Nasogastric sump tubes are generally used with a suction source to facilitate gastric drainage. The primary suction lumen of the tube is used for drainage, the second lumen, the vent lumen, provides an air inlet as a mechanism to break suction minimizing the potential for tube blockage secondary to mucosal tissue invagination into the side holes of the primary suction lumen. With the dual lumen nasogastric sump tube, if the primary lumen becomes obstructed, the gastric contents can back up into the vent lumen causing spillage onto the patient and possible clinical staff exposure to the gastric contents. The PreVent Anti-Reflux Filter provided with the Davol Nasogastric Sump Tube prevents reflux from exiting the vent lumen and spilling from the vent tube. The anti-reflux filter was incorporated for convenience, so that the clinical staff would not have to contend with and be exposed to spilled gastric contents and subsequent patient gown and linen changes. Although spillage from the vent tube is prevented, the user is still able to visualize reflux in the vent tube and therefore, the ability to diagnose a blocked primary lumen is maintained.

**Summary of Similarities and Differences:**

The 510(k) Substantial Equivalence Decision-Making Process (Detailed) decision tree (ODE Guidance Memo #K86-3) was utilized to make a determination of substantial equivalence (see Exhibit VII-2). The answers to the following questions from this decision tree lead to a determination of substantial equivalence.

**1. Does the Device Have Same Indication Statements?**

**Yes.** Both the Davol Nasogastric Sump Tube with PreVent Anti-Reflux Filter and the Predicate Salem are intended for gastric decompression, gastric lavage, and administration of nutritional supplements and medication.

**2. Does New Device Have the Same Technological Characteristics, e.g., Design, Materials, etc.?**

No. Both the Davol Nasogastric Sump Tube with PreVent Anti-Reflux Filter and the Predicate Salem consists of a dual lumen tube (with primary suction lumen and vent lumen) and “side-arm” vent tube connected to the vent lumen. Both nasogastric tubes are provided with an anti-reflux device on the vent tube. Although the nasogastric sump tube components of the two devices are very similar, the technological characteristics of the anti-reflux devices are different.

The Davol Nasogastric Sump Tube with PreVent Anti-Reflux Filter and the Predicate Salem are manufactured from identical material, PVC; are offered in 10, 12 14, 16 and 18 French sizes and in 36 and 48 inches in length; and have a radiopaque stripe. Both devices have five sets of drainage eyes for vacuum sump action; and one eye on the radiopaque stripe. The distal end of the tubes are configured with a tapered funnel for connection to suction systems or standard syringes. Additionally, both devices are sold sterile, for single patient use.

The Davol Nasogastric Sump Tube's PreVent Anti-Reflux Filter is a bidirectional hydrophobic filter with a pore size of 1 micron. The filter housing is manufactured from acrylic plastic while the filter media is manufactured from PTFE. The Predicate Salem's Anti-Reflux valve is a one-way mechanical valve manufactured from plastic material. Both the filter and the valve are intended to contain reflux within the nasogastric tube. Since the Davol Nasogastric Sump Tube's anti-reflux filter allows two-way air flow, reflux may enter the vent tube allowing for visualization of the reflux thus allowing diagnosis of an obstructed primary lumen. The Predicate Salem's anti-reflux valve only allows for one-way air flow into the vent lumen. Air trapped in the vent lumen (between the surface of stomach content and valve base) prevents the rise of gastric content in the vent lumen beyond the point at which trapped air has been compressed.

Both devices require diligent monitoring by the clinical staff to assure proper nasogastric tube function (i.e., adequate gastric fluid/air removal) to help minimize the potential of patient aspiration which may result if the primary suction lumen is obstructed and not cleared. The proposed labeling for the Davol Nasogastric Sump Tube with PreVent Anti-Reflux Filter includes a warning in the Instructions for Use and on the vent tube which reiterates the importance of routine monitoring for gastric reflux.

**3. Could the New Characteristics Affect Safety or Effectiveness?**

Yes. The differences in the configurations of the anti-reflux devices provided with the Davol Nasogastric Sump Tube and the Predicate Salem could affect the ability of the anti-reflux device to contain gastric reflux and allow proper tube function.

4. **Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?**

No. It is generally acknowledged that all nasogastric tubes, whether provided with or without an anti-reflux component, require routine monitoring to assure proper tube function in order to minimize potential complications such as reflux aspiration. Both the Davol Nasogastric Sump Tube PreVent Anti-Reflux Filter and the Predicate Salem Anti-Reflux Valve must prevent stomach reflux from exiting the vent tube without significantly affecting decompression flow rates.

5. **Do Accepted Scientific Methods Exist for Assessing Effect of the New Characteristics?**

Yes. Relatively simple tests methods can be employed to assess the effects of the differences in design between the Davol Nasogastric Sump Tube and the Predicate Salem.

6. **Are Performance Data Available to Assess Effects of New Characteristics?**

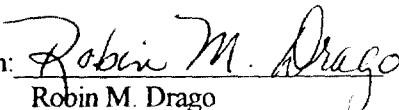
Yes. Laboratory testing has been performed to demonstrate substantial equivalence for specific performance criteria (i.e., flow rates) between the Davol Nasogastric Sump Tube with and without the PreVent Anti-Reflux Filter and the Predicate Salem under simulated clinical conditions. In addition, biocompatibility testing, performed in accordance with ODE memorandum #G95-1 (International Standard ISO-10993, Part 1), has been conducted on the Davol Nasogastric Sump Tube with PreVent Anti-Reflux device.

7. **Does Performance Data Demonstrate Equivalence?**

Yes. Based on the results of the laboratory testing provided in Section V of this submission, the performance characteristics of the Davol Nasogastric Sump Tube with PreVent Anti-Reflux Filter are comparable to that of the currently marketed Predicate Salem. Results from the biocompatibility tests have shown that the materials used to manufacture the Davol Nasogastric Sump Tube with PreVent Anti-Reflux Filter are suitable for the devices intended use as a mucosal contacting device of prolonged duration.

**Conclusion:**

Based on the FDA's decision tree, the subject device, the Davol Nasogastric Sump Tube with PreVent Anti-Reflux Filter, is substantially equivalent to the Predicate Salem.

Contact Person:   
Robin M. Drago

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