510(k) Summary
Antimicrobial Ventilation (Tympanostomy) Tube

K 961873

1.0 Date Prepared

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2.0 Submitter (Contact)

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3.0 Device Name

Proprietary Name:	ACTIVENT Antimicrobial Ventilation Tubes
Common Name:	Tympanostomy (Ventilation) Tube
Classification Name:	Tube, Tympanostomy

5.0 Device Classification

This device was classified by the Ear, Nose and Throat Panel as follows:

Tube, Tympanostomy	77 ETD	Class II 21CFR 874.3880

6.0 Device Description

Each fluoroplastic ACTIVENT tube will be manufactured from a fluoroplastic resin blended with a silver compound and a colorant. This proprietary process results in ventilation tubes that exhibit bacteriocidal/bacterostatic properties. As with the current silicone ACTIVENT tubes, the new fluoroplastic ACTIVENT will be offered in a wide variety of tube designs and sizes (grommets and shank styles) as currently manufactured and distributed in non-antimicrobial vent tubes.

7.0 Intended Use

The intended use of the fluoroplastic antimicrobial vent tube is identical to the currently marketed silicone ACTIVENT tubes: for prescription use only, as a means of temporary communication of the outer and middle ear to provide ventilation or drainage of the middle ear when inserted through an incision in the tympanic membrane.

8.0 Substantial Equivalence

The fluoroplastic ACTIVENT vent tubes are substantially equivalent to the currently marketed silicone ACTIVENT vent tubes. This statement is supported by the fact that both devices have the same intended use / indications for use and contain the same active ingredient. Evaluations of biocompatibility, silver ion leach testing and *in vitro* evaluations of antimicrobial activity were conducted to compare the characteristics of the silicone and fluoroplastic antimicrobial vent tubes. This testing demonstrates that the fluoroplastic tubes display biocompatibility and performance characteristics equivalent to the silicone tubes. Clinical studies or other *in vivo* testing are considered unnecessary, as the clinical safety and effectiveness of silver as an antimicrobial additive has already been demonstrated with the silicone base material as reported in K941407/S1. The equivalent performance and biocompatibility of the fluoroplastic and silicone base materials with silver additive, do not raise any new issues of safety or effectiveness that would require clinical evaluation to resolve.