

**K000801 PC COATED FLUOROPLASTIC VENT TUBES**Jun 19, 2000  
98 days to decisionK000801 · Product code: **ETD** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k000801/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tympanostomy (ETD)
Date received	Mar 13, 2000
Decision date	Jun 19, 2000
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gyrus Ent LLC</b>
Location	Bartlett, TN, US
Contact	ALICIA FARAGE
510(k) history	28 submissions · 28 cleared · 1997-2004

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