

**K983665 MANOMETRIC ASSEMBLIES**May 17, 1999  
210 days to decisionK983665 · Product code: **KLA** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k983665/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Esophageal Motility, Anorectal Motility, And Tube (KLA)
Date received	Oct 19, 1998
Decision date	May 17, 1999
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentsleeve Pty., Ltd.</b>
Location	Golden, CO, US
Contact	MARCUS TIPPETT
510(k) history	3 submissions · 3 cleared · 1998-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983665/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026