

**K082296 COPA AMD**Feb 26, 2009  
198 days to decisionK082296 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k082296/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Aug 12, 2008
Decision date	Feb 26, 2009
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Covidien Lp, Formerly Registered AS Tyco Healthcar</b>
Location	Mansfield, MA, US
Contact	JAMES WELSH
510(k) history	4 submissions · 4 cleared · 2007-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082296/> 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 21, 2026