

**K031339 OPTIBOLUS**Jul 11, 2003  
74 days to decisionK031339 · Product code: **DXT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k031339/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Apr 28, 2003
Decision date	Jul 11, 2003
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mallinckrodt Inc., Liebel-Flarsheim Business</b>
Location	Cincinnati, OH, US
Contact	ELLIS ROGERS
510(k) history	8 submissions · 8 cleared · 1997-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031339/> 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 23, 2026