

**K063503 OPTIVANTAGE DH INJECTOR SYSTEM WITH  
ENHANCED COMMUNICATION**Apr 27, 2007  
158 days to decisionK063503 · Product code: **IZQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k063503/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector, Contrast Medium, Automatic (IZQ)
Date received	Nov 20, 2006
Decision date	Apr 27, 2007
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063503/> Data sourced from FDA 510(k) public records (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. - Generated June 23, 2026