

K984088 OPTISTAR MR INJECTOR SYSTEMDec 6, 1999
385 days to decisionK984088 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k984088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Nov 16, 1998
Decision date	Dec 6, 1999
Days to decision	385 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mallinckrodt Inc., Liebel-Flarsheim Business
Location	Cincinnati, OH, US
Contact	BRIDGET DRAKE
510(k) history	8 submissions · 8 cleared · 1997-2009

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