

K082212 SYRINGE WITH HANDI-FILJan 22, 2009
169 days to decisionK082212 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k082212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Aug 6, 2008
Decision date	Jan 22, 2009
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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