FDA 510(k) Premarket Notification

K031339 OPTIBOLUS

CLEARED

Jul 11, 2003
74 days to decision

K031339 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k031339/

SUBMISSION DETAILS

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

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