FDA 510(k) Premarket Notification

K010708 APPLICATOR TIP/DUAL SPRAYER KIT

CLEARED

Apr 30, 2001
52 days to decision

K010708 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k010708/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Mar 9, 2001
Decision date	Apr 30, 2001
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Interpore Cross Intl.**
Location	Irvine, CA, US
Contact	LYNN M RODARTI
510(k) history	39 submissions · 38 cleared · 1998-2005