FDA 510(k) Premarket Notification

K033039 MODIFICATION TO: ACCUFUSER, ACCUFUSER PLUS, STANDARD PROCEDURE KITS

CLEARED

Oct 7, 2003
8 days to decision

K033039 · Product code: **MEB** · General Hospital
Source: https://www.510kdatabase.net/k033039/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion, Elastomeric (MEB)
Date received	Sep 29, 2003
Decision date	Oct 7, 2003
Days to decision	8 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mckinley, Inc.**
Location	Wheat Ridge, CO, US
Contact	ANDREW N LAMBORNE
510(k) history	7 submissions · 7 cleared · 1998-2004