

K012736 MONOJECT SAFETY NEEDLEOct 25, 2001
70 days to decisionK012736 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k012736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 16, 2001
Decision date	Oct 25, 2001
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tyco Healthcare
Location	Mansfield, MA, US
Contact	DAVID A OLSON
510(k) history	14 submissions · 14 cleared · 2001-2007

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