

K911037 SAFETY NEEDLE SHEATH, MODIFICATIONMay 3, 1991
63 days to decisionK911037 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k911037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 1, 1991
Decision date	May 3, 1991
Days to decision	63 days
Third-party review	No

APPLICANT

Company	Concord/Portex
Location	Keene, NH, US
Contact	ROBERT WHEELER
510(k) history	23 submissions · 20 cleared · 1989-1993

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