FDA 510(k) Premarket Notification

K014073 HYPODERMIC NEEDLE-PRO INSULIN SYRINE & NEEDLE WITH NEEDLE PROTECTION DEVICE

CLEARED

Feb 13, 2002
65 days to decision

K014073 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k014073/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Dec 10, 2001
Decision date	Feb 13, 2002
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Portex, Inc.**
Location	Walker, MI, US
Contact	BRAIN E FARIAS
510(k) history	20 submissions · 20 cleared · 1977-2004