FDA 510(k) Premarket Notification

K052725 PROTECTOR NEEDLE SHEATH PROP

CLEARED

Dec 28, 2005
90 days to decision

K052725 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k052725/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 29, 2005
Decision date	Dec 28, 2005
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Certol International, LLC**
Location	Boulder, CO, US
Contact	LEWIS WARD
510(k) history	1 submissions · 1 cleared · 2005-2005