FDA 510(k) Premarket Notification

K100005 BD PEN NEEDLE

CLEARED

Apr 15, 2010
101 days to decision

K100005 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k100005/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 4, 2010
Decision date	Apr 15, 2010
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Becton, Dickinson and Co.**
Location	Sarasota, FL, US
Contact	James Haynes
510(k) history	6 submissions · 6 cleared · 2001-2015