

**K063450 PORTEX HYPODERMIC NEEDLE- PRO EDGE SAFETY
DEVICE, 18GX1, 401810, 19GX1, 401910, 20GX1,402010,
21GX1402110**Jan 25, 2007
71 days to decisionK063450 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k063450/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 15, 2006
Decision date	Jan 25, 2007
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smiths Medical Asd, Inc.
Location	Rockland, MA, US
Contact	BRIAN FARIAS
510(k) history	52 submissions · 52 cleared · 2004-2024

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