

K070988 SC PROFI FINE PEN NEEDLE, MODELSAug 23, 2007
139 days to decisionK070988 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k070988/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 6, 2007
Decision date	Aug 23, 2007
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary
Other names	5MM, 8MM, 12.7MM (28G, 29G, 30G, 31G)

APPLICANT

Company	Shinchang Medical Co., Ltd.
Location	Salt Lake City, UT, US
Contact	JAN J FRANK
510(k) history	3 submissions · 3 cleared · 2000-2007

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Device record: <https://www.510kdatabase.net/k070988/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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