

K152597 ProteXsure Safety Capsule SystemJun 8, 2016
271 days to decisionK152597 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k152597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 11, 2015
Decision date	Jun 8, 2016
Days to decision	271 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Starcap Medical, LLC (Db a Prism Medical & Design)
Location	Parkland, FL, US
Contact	Les Capella
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152597/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026