

K153388 IMPROSAFE Blood Collection Set with Pre-attached Holder, IMPROVACUTER Blood Collection Set Pre-attached Holder, IMPROSAFE Blood Collection Set, IMPROVACUTER Blood Collection Set, IMPROSAFE Multi Sample Needle, IMPROSAFE Multi Sample Needle (Flashback), IMPROVACUTER Multi Sample NeedleJun 7, 2016
197 days to decisionK153388 · Product code: FMI · General Hospital
Source: <https://www.510kdatabase.net/k153388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 23, 2015
Decision date	Jun 7, 2016
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Improve Medical Instruments Co., Ltd.
Location	Shanghai, CN
Contact	BANGFU SUN
Website	http://www.improve-medical.com/
510(k) history	2 submissions · 2 cleared · 2010-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153388/> 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