

K181447 Safety insulin needle for single useMar 12, 2019
284 days to decisionK181447 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k181447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 1, 2018
Decision date	Mar 12, 2019
Days to decision	284 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Berpu Medical Technology Co., Ltd.
Location	Wenzhou, CN
Contact	Jundong Tan
510(k) history	9 submissions · 9 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181447/> 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 May 26, 2026