

K133075 Plus Surgical Gowns (EO Sterilized), PMGB-XXXJun 24, 2015
632 days to decisionK133075 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k133075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 30, 2013
Decision date	Jun 24, 2015
Days to decision	632 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Foshan Nanhai Plus Medical Co, Ltd.
Location	Dover, DE, US
Contact	LEON LU
510(k) history	8 submissions · 8 cleared · 2015-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133075/> 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