

K152803 SUNGSHIM STERILE SINGLE USE INSULIN SYRINGEJul 12, 2016
288 days to decisionK152803 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k152803/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 28, 2015
Decision date	Jul 12, 2016
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sung Shim Medicare Co., Ltd.
Location	Sejing-Si, KR
Contact	KIM YOUNG KWAN
510(k) history	2 submissions · 2 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152803/> 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