

K181369 Immucise Intradermal Injection SystemNov 13, 2018
174 days to decisionK181369 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k181369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 23, 2018
Decision date	Nov 13, 2018
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Corporation
Location	Shibuya-Ku, Tokyo, JP
Contact	Yuko Watanabe
510(k) history	13 submissions · 13 cleared · 2012-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181369/> 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 24, 2026