FDA 510(k) Premarket Notification

K181369 Immucise Intradermal Injection System

CLEARED

Nov 13, 2018
174 days to decision

K181369 · 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