FDA 510(k) Premarket Notification

K231095 Tamper Evident Cap

CLEARED

Sep 4, 2024
505 days to decision

K231095 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k231095/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 18, 2023
Decision date	Sep 4, 2024
Days to decision	505 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**International Medical Industries, Inc.**
Location	Pompano Beach, FL, US
Contact	David Meily
510(k) history	7 submissions · 7 cleared · 2017-2024