FDA 510(k) Premarket Notification

K210037 Pluski Safe 1 Safety IV Catheter

CLEARED

Mar 25, 2022
443 days to decision

K210037 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k210037/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jan 6, 2021
Decision date	Mar 25, 2022
Days to decision	443 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mediplus (India) Limited**
Location	Bahadurgarh, IN
Contact	Alka Goel
510(k) history	1 submissions · 1 cleared · 2022-2022