FDA 510(k) Premarket Notification

K223353 DropSafeTM SicuraTM

CLEARED

Dec 2, 2022
30 days to decision

K223353 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k223353/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 2, 2022
Decision date	Dec 2, 2022
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pikdare Spa**
Location	Casnate Con Bernate, IT
Contact	Roberta Zanoni
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov