FDA 510(k) Premarket Notification

K210399 Unifine SafeControl

CLEARED

Sep 17, 2021
219 days to decision

K210399 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k210399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 10, 2021
Decision date	Sep 17, 2021
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Owen Mumford, Ltd.**
Location	Marietta, GA, US
Contact	Darren Mansell
Website	http://www.owenmumford.com/us/
510(k) history	13 submissions · 13 cleared · 2000-2023

Owen Mumford, Ltd. is a global medical device manufacturer with over 70 years of experience designing and manufacturing innovative healthcare solutions. The company specializes in drug delivery systems, blood collection devices, and safety lancets for both clinical and home use. Owen Mumford operates with a manufacturing facility in Marietta, US, and serves healthcare professionals and patients worldwide. The company has received FDA 510(k) clearances from total submissions, spanning from 2000 to 2023. Owen Mumford's cleared devices focus primarily on General Hospital app...