FDA 510(k) Premarket Notification

CLEARED

K173881 Unifine SafeControl 5mm x 30G, Unifine SafeControl 8mm x 30G

Jul 11, 2018
202 days to decision

K173881 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k173881/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 21, 2017
Decision date	Jul 11, 2018
Days to decision	202 days
Third-party review	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...