

K152339 Unifine Pentips/ Unifine Pentips PlusJun 24, 2016
310 days to decisionK152339 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k152339/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 19, 2015
Decision date	Jun 24, 2016
Days to decision	310 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Owen Mumford, Ltd.
Location	Marietta, GA, US
Contact	Patty Cronan
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...
