FDA 510(k) Premarket Notification

K213407 UltiCare Disposable Pen Needles

CLEARED

Dec 16, 2021
58 days to decision

K213407 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k213407/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 19, 2021
Decision date	Dec 16, 2021
Days to decision	58 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ultimed Incorporated**
Location	Minneapolis, MN, US
Contact	Paul Lewis
510(k) history	2 submissions · 2 cleared · 2015-2021

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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