

K222168 Unistik TinyTouch Sterile Single-Use Heel Incision Safety Lancets - Premie and Full-Term, Unistik Heelstik Sterile Single-Use Heel Incision Safety Lancets - MicroPremie, Premie, Full-Term and Toddler

Nov 3, 2022
105 days to decision

K222168 · Product code: **FMK** · General & Plastic Surgery

Source: <https://www.510kdatabase.net/k222168/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Jul 21, 2022
Decision date	Nov 3, 2022
Days to decision	105 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k222168/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026