

K231124 Unistik® 3 Single-Use Safety Lancets:- Extra (21G), Normal (23G), Comfort (28G), Gentle (30G)Jun 27, 2023
68 days to decisionK231124 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231124/>**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	Apr 20, 2023
Decision date	Jun 27, 2023
Days to decision	68 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...

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Device record: <https://www.510kdatabase.net/k231124/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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