

**K221126 Unistik® 3, sterile single-use safety lancets**Aug 12, 2022  
116 days to decisionK221126 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221126/>**SUBMISSION DETAILS**

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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 18, 2022
Decision date	Aug 12, 2022
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Unistik® 3 Value, sterile single-use safety lancets; Abbott SF sterile single-use safety lancets

**APPLICANT**

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Company	<b>Owen Mumford, Ltd.</b>
Location	Marietta, GA, US
Contact	Darren Mansell
Website	<a href="http://www.owenmumford.com/us/">http://www.owenmumford.com/us/</a>
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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