

**K222303 Unistik® Pro**Oct 25, 2022  
85 days to decisionK222303 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222303/>**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	Aug 1, 2022
Decision date	Oct 25, 2022
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**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...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Owen Mumford USA, Inc.</b>
Contact	Patty Cronan

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k222303/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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