FDA 510(k) Premarket Notification

K000482 MODIFICATION TO AUTOJECT MINI

CLEARED

Mar 6, 2000
21 days to decision

K000482 · Product code: **KZH** · General Hospital
Source: https://www.510kdatabase.net/k000482/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Feb 14, 2000
Decision date	Mar 6, 2000
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Owen Mumford, Ltd.**
Location	Marietta, GA, US
Contact	ROBERT SHAW
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/k000482/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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