

**K110042 MANUKATEX**Mar 24, 2011  
77 days to decisionK110042 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k110042/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jan 6, 2011
Decision date	Mar 24, 2011
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Manuka Medical Limited</b>
Location	Laguna Niguel, CA, US
Contact	James Smith
510(k) history	3 submissions · 3 cleared · 2010-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110042/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026