

K133729 WOUND DRESSING WITH MANUKA HONEYJan 23, 2015
413 days to decisionK133729 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k133729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Dec 6, 2013
Decision date	Jan 23, 2015
Days to decision	413 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Manuka Health New Zealand , Ltd.
Location	Bridgewater, NJ, US
Contact	DAVID BECHTEL
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133729/> Data sourced from FDA 510(k) public records (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. - Generated June 5, 2026