

**K080949 KERATEC WOUND DRESSINGS**Feb 11, 2009  
314 days to decisionK080949 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k080949/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Apr 3, 2008
Decision date	Feb 11, 2009
Days to decision	314 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Keratec Limited</b>
Location	North Attleboro, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	1 submissions · 1 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080949/> 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 23, 2026