

**K931828 CARELET SAFETY LANCET**Oct 15, 1993  
190 days to decisionK931828 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k931828/>**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	Apr 8, 1993
Decision date	Oct 15, 1993
Days to decision	190 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Gainor Medical Europe, Ltd.</b>
Location	Mcdonough, GA, US
Contact	MARK J GAINOR
510(k) history	13 submissions · 13 cleared · 1990-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k931828/> 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 May 26, 2026