

**K850100 BLOOD LANCET**Jan 29, 1987  
748 days to decisionK850100 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k850100/>**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	Jan 11, 1985
Decision date	Jan 29, 1987
Days to decision	748 days
Third-party review	No

**APPLICANT**

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Company	<b>Gainor Medical</b>
Location	US
Contact	MARK GAINOR
510(k) history	11 submissions · 11 cleared · 1984-1987

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850100/>; 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 29, 2026