

**K902416 SURELITE AND SURELITE XL BLOOD LANCET**Aug 1, 1990  
62 days to decisionK902416 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k902416/>**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	May 31, 1990
Decision date	Aug 1, 1990
Days to decision	62 days
Third-party review	No

**APPLICANT**

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Company	<b>Gainor Medical Europe, Ltd.</b>
Location	Mcdonough, GA, US
Contact	MARK 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/k902416/>; 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