

**K123038 SWISS LITHOBREAKER**Jan 16, 2013  
110 days to decisionK123038 · Product code: **FFK** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k123038/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, Electro-hydraulic (FFK)
Date received	Sep 28, 2012
Decision date	Jan 16, 2013
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>E.M.S Electro Medical Systems S.A</b>
Location	North Attleboro, MA, US
Contact	SUZANNE GOODMAN
510(k) history	28 submissions · 28 cleared · 2005-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123038/> 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 9, 2026