

**K161305 Habib EUS RFA**Jul 7, 2016  
58 days to decisionK161305 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161305/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	May 10, 2016
Decision date	Jul 7, 2016
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Emcision , Ltd.</b>
Location	London, GB
Contact	FRANCOIS POULIN
510(k) history	10 submissions · 10 cleared · 2005-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161305/> 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 30, 2026