

**K182605 HS AMICA devices family**Oct 28, 2019  
402 days to decisionK182605 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182605/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 21, 2018
Decision date	Oct 28, 2019
Days to decision	402 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>H.S Hospital Service S.P.A</b>
Location	Boca Raton, FL, US
Contact	Laura Lenzi
510(k) history	6 submissions · 6 cleared · 2004-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182605/> 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