

**K211344 MICRUSFRAME, DELTAFILL, DELTAXSFT, GALAXY G3, GALAXY G3 XSFT, and GALAXY G3 Mini Microcoil Delivery Systems**May 28, 2021  
25 days to decisionK211344 · Product code: **HCG** · Neurology  
Source: <https://www.510kdatabase.net/k211344/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	May 3, 2021
Decision date	May 28, 2021
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medos International SARL</b>
Location	Raynham, MA, US
Contact	Ariell Joiner
510(k) history	96 submissions · 96 cleared · 2010-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Cerenovus</b>
Contact	Ariell Joiner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211344/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026