

**K080967 TRUFILL DCS ORBIT DETACHABLE COIL AND TRUFILL DCS SYRINGE OR TRUFILL DCS SYRINGE II, ALSO KNOWN AS THE TRUFILL DCS ORBIT**May 2, 2008  
28 days to decisionK080967 · Product code: **HCG** · Neurology  
Source: <https://www.510kdatabase.net/k080967/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Apr 4, 2008
Decision date	May 2, 2008
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cordis Neurovascular, Inc.</b>
Location	Miami Lakes, FL, US
Contact	Amarilys Machado
510(k) history	37 submissions · 37 cleared · 1994-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080967/>; 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 24, 2026