

**K053197 TRUFILL DCS ORBIT DETACHABLE COIL SYSTEM
LINE EXTENSION**Dec 15, 2005
29 days to decisionK053197 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k053197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Nov 16, 2005
Decision date	Dec 15, 2005
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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