

**K964021 INTRAMED SIDE BRANCH OCCLUSION (SBO)  
SYSTEM (700095 AND 700099)**Mar 27, 1997  
171 days to decisionK964021 · Product code: **HCG** · Neurology  
Source: <https://www.510kdatabase.net/k964021/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Oct 7, 1996
Decision date	Mar 27, 1997
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baxter Edwards</b>
Location	Irvine, CA, US
Contact	PAULA A TORRIANNI
510(k) history	11 submissions · 10 cleared · 1993-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964021/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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