

**K944858 BAXTER EPTFE EXTERNALLY SUPPORTED  
VASCULAR GRAFTS**Jan 5, 1995  
94 days to decisionK944858 · Product code: **DSY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k944858/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Oct 3, 1994
Decision date	Jan 5, 1995
Days to decision	94 days
Third-party review	No

**APPLICANT**

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Company	<b>Baxter Edwards</b>
Location	Irvine, CA, US
Contact	ESTHER SALTZ
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/k944858/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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