

**K881279 EDWARDS-DUROMEDICS BILEAFLET VALVE SIZER SET**May 18, 1988  
57 days to decisionK881279 · Product code: **DTI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k881279/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sizer, Heart-valve, Prosthesis (DTI)
Date received	Mar 22, 1988
Decision date	May 18, 1988
Days to decision	57 days
Third-party review	No

**APPLICANT**

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Company	<b>Baxter Healthcare Corp</b>
Location	Mchenry, IL, US
Contact	JOHN L ELY
510(k) history	505 submissions · 496 cleared · 1977-2019

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k881279/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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