

K881449 EDWARDS-DUROMEDICS LEAFLET PROBE, MODEL 1116Jun 15, 1988
71 days to decisionK881449 · Product code: **LXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k881449/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Test, Heart-valve (LXN)
Date received	Apr 5, 1988
Decision date	Jun 15, 1988
Days to decision	71 days
Third-party review	No

APPLICANT

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

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