

K810894 FOGARTY FLEXIBLE CALIBRATORMay 15, 1981
42 days to decisionK810894 · Product code: **DWP** · CardiovascularSource: <https://www.510kdatabase.net/k810894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, Surgical (DWP)
Date received	Apr 3, 1981
Decision date	May 15, 1981
Days to decision	42 days
Third-party review	No

APPLICANT

Company	American Edwards Laboratories
Location	Walker, MI, US
510(k) history	89 submissions · 88 cleared · 1980-1987

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Device record: <https://www.510kdatabase.net/k810894/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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