

K833997 CO-SETApr 17, 1984
148 days to decisionK833997 · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k833997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Nov 21, 1983
Decision date	Apr 17, 1984
Days to decision	148 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/k833997/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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