

**K864155 MODIFICATION OF CARPENTIER-EDWARDS
BIOPROSTHESIS**Nov 20, 1986
28 days to decisionK864155 · Product code: **DTJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k864155/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holder, Heart-valve, Prosthesis (DTJ)
Date received	Oct 23, 1986
Decision date	Nov 20, 1986
Days to decision	28 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864155/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026