FDA 510(k) Premarket Notification

K833763 PERICARDIAL PATCH

CLEARED

Nov 1, 1984
372 days to decision

K833763 · Product code: **DXZ** · Cardiovascular
Source: https://www.510kdatabase.net/k833763/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfe, Polypropylene (DXZ)
Date received	Oct 26, 1983
Decision date	Nov 1, 1984
Days to decision	372 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k833763/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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