FDA 510(k) Premarket Notification

K830728 CARDIOVASCULAR DISPOSABLE PRODUCTS

CLEARED

Apr 28, 1983
51 days to decision

K830728 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k830728/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Mar 8, 1983
Decision date	Apr 28, 1983
Days to decision	51 days
Third-party review	No

APPLICANT

Company	**Electromics, Inc.**
Location	Walker, MI, US
510(k) history	2 submissions · 2 cleared · 1983-1983

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k830728/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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