FDA 510(k) Premarket Notification

K855004 SWELL-RELIEF

CLEARED

Feb 12, 1986
61 days to decision

K855004 · Product code: **DRM** · Cardiovascular
Source: https://www.510kdatabase.net/k855004/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Compressor, Cardiac, External (DRM)
Date received	Dec 13, 1985
Decision date	Feb 12, 1986
Days to decision	61 days
Third-party review	No

APPLICANT

Company	**D.A. Schulman, Inc.**
Location	Mchenry, IL, US
Contact	DAVID A SCHULMAN
510(k) history	4 submissions · 4 cleared · 1983-1988