FDA 510(k) Premarket Notification

K860497 CAROTID BALLOON SHUNT

CLEARED

May 28, 1986
107 days to decision

K860497 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k860497/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Feb 10, 1986
Decision date	May 28, 1986
Days to decision	107 days
Third-party review	No

APPLICANT

Company	**Imodex, Inc.**
Location	St. Clair Shores, MI, US
Contact	SHELDON DAVIS
510(k) history	2 submissions · 2 cleared · 1986-1988