FDA 510(k) Premarket Notification

K853101 VASCUTER EXTERNAL REINFORCE TRIAXIAL PROSTHESES

CLEARED

Feb 24, 1986
216 days to decision

K853101 · Product code: **DSY** · Cardiovascular
Source: https://www.510kdatabase.net/k853101/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Jul 23, 1985
Decision date	Feb 24, 1986
Days to decision	216 days
Third-party review	No

APPLICANT

Company	**Cobe Laboratories, Inc.**
Location	Mchenry, IL, US
Contact	VERA BUFFALOE
Website	https://www.gambro.com
510(k) history	77 submissions · 77 cleared · 1976-1993

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k853101/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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