FDA 510(k) Premarket Notification

K822033 BERMAN ANGIOGRAPHIC BALLOON CATHETER

CLEARED

Aug 24, 1982
43 days to decision

K822033 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k822033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jul 12, 1982
Decision date	Aug 24, 1982
Days to decision	43 days
Third-party review	No

APPLICANT

Company	**Ziehm International, Inc.**
Location	Annapolis, MD, US
510(k) history	16 submissions · 16 cleared · 1982-2001