FDA 510(k) Premarket Notification

K874738 10 AND 12 FRENCH VESSEL DILATORS

CLEARED

May 2, 1988
166 days to decision

K874738 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k874738/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 18, 1987
Decision date	May 2, 1988
Days to decision	166 days
Third-party review	No

APPLICANT

Company	**Impra, Inc.**
Location	Mchenry, IL, US
Contact	JAMES M MCHANEY
510(k) history	29 submissions · 24 cleared · 1979-2001