FDA 510(k) Premarket Notification

K905416 VESSEL DILATOR

CLEARED

Mar 25, 1991
111 days to decision

K905416 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k905416/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Dec 4, 1990
Decision date	Mar 25, 1991
Days to decision	111 days
Third-party review	No

APPLICANT

Company	**The R Group**
Location	Gainesvilles, FL, US
Contact	MARK J KAHN
510(k) history	4 submissions · 4 cleared · 1991-1991