FDA 510(k) Premarket Notification

K901815 MODIFIED STERILIZATION OF INTRA-ART(TM) CORONARY

CLEARED

Jul 3, 1990
71 days to decision

K901815 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k901815/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Apr 23, 1990
Decision date	Jul 3, 1990
Days to decision	71 days
Third-party review	No

APPLICANT

Company	**Pioneering Technologies, Inc.**
Location	Martinez, CA, US
Contact	WRIGHT,PHD
510(k) history	19 submissions · 19 cleared · 1988-1992

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k901815/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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