FDA 510(k) Premarket Notification

K963388 VESSEL DILATOR

CLEARED

Mar 11, 1997
195 days to decision

K963388 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k963388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Aug 28, 1996
Decision date	Mar 11, 1997
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Maxxim Medical**
Location	Arlington, TX, US
Contact	RICHARD A HAMER
510(k) history	26 submissions · 25 cleared · 1994-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k963388/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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