FDA 510(k) Premarket Notification

K050629 ANGIOSCULPT SCORING BALLOON CATHETER

CLEARED

Sep 2, 2005
175 days to decision

K050629 · Product code: **PNO** · Cardiovascular
Source: https://www.510kdatabase.net/k050629/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Mar 11, 2005
Decision date	Sep 2, 2005
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Angioscore, Inc.**
Location	Alameda, CA, US
Contact	GARY GERSHONY
510(k) history	13 submissions · 13 cleared · 2005-2015