FDA 510(k) Premarket Notification

K081220 MODIFICATION TO ANGIOSCULPT PTA SCORING BALLOON CATHETER

CLEARED

May 28, 2008
28 days to decision

K081220 · Product code: **PNO** · Cardiovascular
Source: https://www.510kdatabase.net/k081220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Apr 30, 2008
Decision date	May 28, 2008
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k081220/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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