K100303 ANGIOSCULPT PTA SCORING BALLOON CATHETER MODEL 2039-XXYY, 2076-XXYY, 2092-XXYY, 2105-XXYY

CLEARED

Mar 22, 2010
47 days to decision

K100303 · Product code: **PNO** · Cardiovascular
Source: https://www.510kdatabase.net/k100303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Feb 3, 2010
Decision date	Mar 22, 2010
Days to decision	47 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