

**K100303 ANGIOSCULPT PTA SCORING BALLOON CATHETER
MODEL 2039-XXYY, 2076-XXYY, 2092-XXYY, 2105-XXYY**Mar 22, 2010
47 days to decisionK100303 · 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100303/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 5, 2026