

**K221986 XO Score LP Percutaneous Transluminal Angioplasty
Scoring Catheter, XO Score LP Catheter**Oct 18, 2022
104 days to decisionK221986 · Product code: **PNO** · Cardiovascular
Source: <https://www.510kdatabase.net/k221986/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Jul 6, 2022
Decision date	Oct 18, 2022
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Transit Scientific, LLC
Location	Salt Lake City, UT, US
Contact	Jennifer Arnold
510(k) history	5 submissions · 5 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	University of Utah
Contact	Spencer Walker

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221986/> 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 May 24, 2026