FDA 510(k) Premarket Notification

CLEARED

K232258 XO Constrain™ Percutaneous Transluminal Angioplasty Constraining Catheter

Jun 17, 2024
322 days to decision

K232258 · Product code: **PNO** · Cardiovascular
Source: https://www.510kdatabase.net/k232258/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Jul 31, 2023
Decision date	Jun 17, 2024
Days to decision	322 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	Lilly Myers
510(k) history	5 submissions · 5 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**University of Utah, Center For Medical Innovation**
Contact	Spencer Walker

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov