

K220634 NC TREK NEO Coronary Dilatation CatheterJun 30, 2022
118 days to decisionK220634 · Product code: **LOX** · CardiovascularSource: <https://www.510kdatabase.net/k220634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Mar 4, 2022
Decision date	Jun 30, 2022
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Vascular
Location	S,Mta Clara, CA, US
Contact	Nishi Singh
510(k) history	30 submissions · 30 cleared · 2009-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220634/> 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 14, 2026