

K241478 Tri-Wedge PTA Scoring Balloon Dilatation CatheterOct 22, 2024
151 days to decisionK241478 · Product code: **PNO** · Cardiovascular
Source: <https://www.510kdatabase.net/k241478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	May 24, 2024
Decision date	Oct 22, 2024
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Brosmed Medical Co., Ltd.
Location	Dongguan, CN
Contact	Crystal Lee
510(k) history	8 submissions · 8 cleared · 2016-2025

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