

K242254 D-Kutting™ LL Peripheral Scoring Balloon Dilatation CatheterApr 21, 2025
264 days to decisionK242254 · Product code: **PNO** · Cardiovascular
Source: <https://www.510kdatabase.net/k242254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Jul 31, 2024
Decision date	Apr 21, 2025
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dk Medical Technology Co., Ltd.
Location	Suzhou, CN
Contact	Quan Shi
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Dk Medtech Singapore Pte. , Ltd.
Contact	Quan Shi

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

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