FDA 510(k) Premarket Notification

CLEARED

K242254 D·Kutting™ LL Peripheral Scoring Balloon Dilatation Catheter

Apr 21, 2025
264 days to decision

K242254 · 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