FDA 510(k) Premarket Notification

CLEARED

K232207 D·Kutting™ PTA Scoring Balloon Dilatation Catheter

Mar 7, 2024
225 days to decision

K232207 · Product code: **PNO** · Cardiovascular
Source: https://www.510kdatabase.net/k232207/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Jul 26, 2023
Decision date	Mar 7, 2024
Days to decision	225 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	Shi Quan
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**Microkn Medical Technology Service (Shanghai) Co., Ltd.**
Contact	Heather Wang

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