

**K232207 D-Kutting™ PTA Scoring Balloon Dilatation Catheter**Mar 7, 2024  
225 days to decisionK232207 · Product code: **PNO** · CardiovascularSource: <https://www.510kdatabase.net/k232207/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Microkn Medical Technology Service (Shanghai) Co., Ltd.</b>
Contact	Heather Wang

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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