

K214009 D-Kaptain PTA High Pressure Balloon Dilatation CatheterApr 5, 2023
516 days to decisionK214009 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k214009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Nov 5, 2021
Decision date	Apr 5, 2023
Days to decision	516 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 Business Consulting (Shanghai) Co., Ltd.
Contact	Yuling Chen

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

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