

K212215 Tiche PTA Balloon Dilatation CatheterJul 19, 2022
369 days to decisionK212215 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k212215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jul 15, 2021
Decision date	Jul 19, 2022
Days to decision	369 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Brosmed Medical Co., Ltd.
Location	Dongguan, CN
Contact	Crystal Lee
510(k) history	8 submissions · 8 cleared · 2016-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212215/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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