

K243704 Parafleet SC 014 PTA Balloon Dilatation CatheterFeb 27, 2025
90 days to decisionK243704 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k243704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Nov 29, 2024
Decision date	Feb 27, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Parafleet SC 018 PTA Balloon Dilatation Catheter; Parafleet SC 035 PTA Balloon Dilatation Catheter

APPLICANT

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

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