

K201246 PTA Balloon Catheter (PVQ), MIT PTA Balloon Catheter (PVQ)Aug 3, 2021
452 days to decisionK201246 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k201246/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 8, 2020
Decision date	Aug 3, 2021
Days to decision	452 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qualimed USA, LLC
Location	Charlotte, NC, US
Contact	Manfred Gulcher
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Alston & Bird, LLP
Contact	Marc J. Scheineson

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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