

K173894 Jade PTA Balloon Dilatation CatheterFeb 9, 2018
50 days to decisionK173894 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k173894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Dec 21, 2017
Decision date	Feb 9, 2018
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orbusneich Medical Trading, Inc.
Location	Fort Lauderdale, FL, US
Contact	John Pazienza
510(k) history	7 submissions · 7 cleared · 2018-2020

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