

**K103354 EBONY PTA .035 PERIPHERAL DILATATION
CATHETER**Feb 23, 2011
99 days to decisionK103354 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k103354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Nov 16, 2010
Decision date	Feb 23, 2011
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Natec Medical , Ltd.
Location	Crofton, MD, US
Contact	E.J. Smith
510(k) history	11 submissions · 11 cleared · 2011-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103354/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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