

K143041 Ebony PTA 0.014''' over the wire Catheter and Ebony PTA 0.018 over the wire Catheter

Jun 4, 2015
225 days to decision

K143041 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k143041/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Oct 22, 2014
Decision date	Jun 4, 2015
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Natec Medical , Ltd.
Location	Crofton, MD, US
Contact	Xavier De Buchere
510(k) history	11 submissions · 11 cleared · 2011-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k143041/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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