

K220410 Ebony HP PTA OTW 0.035 CatheterJun 29, 2022
135 days to decisionK220410 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k220410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Feb 14, 2022
Decision date	Jun 29, 2022
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Natec Medical , Ltd.
Location	Crofton, MD, US
Contact	Roy Devassy Pallippatt
510(k) history	11 submissions · 11 cleared · 2011-2025

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