

K210012 Tamarin Blue PTCA RX Dilatation CatheterJul 9, 2021
186 days to decisionK210012 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k210012/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX) |
| Date received | Jan 4, 2021 |
| Decision date | Jul 9, 2021 |
| Days to decision | 186 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 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | CardioMed Device Consultants, LLC |
| Contact | Candace Cederman |

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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