

**K181023 Mozec – Rx PTCA Balloon Dilatation Catheter, Mozec
NC – Rx PTCA Balloon Dilatation Catheter**May 17, 2018
30 days to decisionK181023 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k181023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Apr 17, 2018
Decision date	May 17, 2018
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Meril Life Sciences Private Limited
Location	Baltimore, MD, US
Contact	Utpal Thakor
510(k) history	4 submissions · 4 cleared · 2013-2019

REGULATORY CONSULTANT

Consulting firm	CardioMed Device Consultants, LLC
Contact	H. Semith Oktay

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181023/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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