

K252295 RyureiMar 27, 2026
247 days to decisionK252295 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k252295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Jul 23, 2025
Decision date	Mar 27, 2026
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Corporation
Location	Shibuya-Ku, Tokyo, JP
Contact	Kirsten Steinmann
510(k) history	13 submissions · 13 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	Terumo Medical Corporation
Contact	Kirsten Steinmann

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

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