

K163372 RX Takeru Balloon Dilatation CatheterApr 7, 2017
127 days to decisionK163372 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k163372/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Dec 1, 2016
Decision date	Apr 7, 2017
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	KANEKA Corporation
Location	Tokyo, JP
Contact	Toshihiko Motomine
510(k) history	10 submissions · 10 cleared · 2015-2018

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