

K170941 RX NC Takeru PTCA Balloon Dilatation CatheterJul 7, 2017
99 days to decisionK170941 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k170941/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Mar 30, 2017
Decision date	Jul 7, 2017
Days to decision	99 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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