

K161546 R2P SlenGuideOct 14, 2016
133 days to decisionK161546 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k161546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 3, 2016
Decision date	Oct 14, 2016
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ashitaka Factory of Terumo Corporation
Location	Fujinomiya Shizuoka, JP
Contact	PHEBE VARGHESE
510(k) history	3 submissions · 3 cleared · 2016-2021

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