

K161679 s LDL-EX SEIKENAug 18, 2017
427 days to decisionK161679 · Product code: **PYP** · Chemistry
Source: <https://www.510kdatabase.net/k161679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low-density Lipoprotein (Ldl) Cholesterol Sub-fraction Test (PYP)
Date received	Jun 17, 2016
Decision date	Aug 18, 2017
Days to decision	427 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Denka Seiken Co., Ltd.
Location	Gosen City, Niigata, JP
Contact	Takayoshi Ishii
510(k) history	6 submissions · 6 cleared · 2003-2017

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