

K180835 SEKURE Acetaminophen L3K AssayFeb 8, 2019
315 days to decisionK180835 · Product code: **LDP** · Toxicology
Source: <https://www.510kdatabase.net/k180835/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetry, Acetaminophen (LDP)
Date received	Mar 30, 2018
Decision date	Feb 8, 2019
Days to decision	315 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sekisui Diagnostics P.E.I., Inc.
Location	Prince Edward Island, CA
Contact	Penny White
510(k) history	6 submissions · 6 cleared · 2011-2022

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