

K182702 SEKURE Creatine Kinase AssayApr 17, 2019
202 days to decisionK182702 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k182702/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Sep 27, 2018
Decision date	Apr 17, 2019
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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