

K161527 Teco Creatinine Enzymatic Reagent KitJul 21, 2017
414 days to decisionK161527 · Product code: **JFY** · Chemistry
Source: <https://www.510kdatabase.net/k161527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Jun 2, 2016
Decision date	Jul 21, 2017
Days to decision	414 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teco Diagnostics, Inc.
Location	Anaheim, CA, US
Contact	XIAOYAN HU
510(k) history	4 submissions · 4 cleared · 2016-2017

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