

K212223 Atellica CH Enzymatic Creatinine_3 (ECre3)Nov 24, 2021
131 days to decisionK212223 · Product code: **JFY** · Chemistry
Source: <https://www.510kdatabase.net/k212223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Jul 16, 2021
Decision date	Nov 24, 2021
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Ian Thompson
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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