

K191454 Atellica CH Amylase_2 (AMY_2)Jul 30, 2019
60 days to decisionK191454 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k191454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	May 31, 2019
Decision date	Jul 30, 2019
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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