

K222104 Atellica® CH Diazo Total Bilirubin (D_TBil)Mar 20, 2023
245 days to decisionK222104 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k222104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jul 18, 2022
Decision date	Mar 20, 2023
Days to decision	245 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	Anthony Calabro
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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