FDA 510(k) Premarket Notification

CLEARED

K261364 Atellica CH Acetaminophen 2 (ACTM)

Jul 24, 2026
88 days to decision

K261364 · Product code: **LDP** · Chemistry
Source: https://www.510kdatabase.net/k261364/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetry, Acetaminophen (LDP)
Date received	Apr 27, 2026
Decision date	Jul 24, 2026
Days to decision	88 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	Kelly Maher
Website	https://www.siemens-healthineers.com
510(k) history	153 submissions · 152 cleared · 2008-2026