

**K221605 Emit® II Plus Buprenorphine Assay**Jul 25, 2023  
418 days to decisionK221605 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k221605/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jun 2, 2022
Decision date	Jul 25, 2023
Days to decision	418 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics, Inc.</b>
Location	New York, NY, US
Contact	Julie Warren
Website	<a href="https://www.siemens-healthineers.com">https://www.siemens-healthineers.com</a>
510(k) history	152 submissions · 151 cleared · 2008-2026

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