

**K250609 Sober Self-Test**Sep 15, 2025  
199 days to decisionK250609 · Product code: **DIC** · Toxicology  
Source: <https://www.510kdatabase.net/k250609/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method (DIC)
Date received	Feb 28, 2025
Decision date	Sep 15, 2025
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sober Ip, LLC</b>
Location	Southfield, MI, US
Contact	Timothy Downey
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Synergy Bioscience</b>
Contact	Shadeed Salem

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250609/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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