

**K854163 TDX COCAINE METABOLITE**Nov 5, 1985  
21 days to decisionK854163 · Product code: **DIO** · Chemistry  
Source: <https://www.510kdatabase.net/k854163/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Oct 15, 1985
Decision date	Nov 5, 1985
Days to decision	21 days
Third-party review	No

**APPLICANT**

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Company	<b>Abbott Laboratories</b>
Location	Abbott Park, IL, US
Contact	MARY E ZORC
Website	<a href="http://www.abbott.com">http://www.abbott.com</a>
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

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Device record: <https://www.510kdatabase.net/k854163/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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