

**K003583 LITHIUM REGENT MODEL TR66056 / LITHIUM  
STANDARD TR66901**Jan 17, 2001  
58 days to decisionK003583 · Product code: **NDW** · Chemistry  
Source: <https://www.510kdatabase.net/k003583/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Porphyrin, Spectrophotometry, Lithium (NDW)
Date received	Nov 20, 2000
Decision date	Jan 17, 2001
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Trace America, Inc.</b>
Location	Miami, FL, US
Contact	THOMAS DOLLAR
510(k) history	22 submissions · 22 cleared · 1988-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003583/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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