

**K880794 RESUBMITTED BICARBONATE (CO2) REAGENT  
SINGLE VIAL**Apr 18, 1988  
52 days to decisionK880794 · Product code: **KHS** · Chemistry  
Source: <https://www.510kdatabase.net/k880794/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic, Carbon-dioxide (KHS)
Date received	Feb 26, 1988
Decision date	Apr 18, 1988
Days to decision	52 days
Third-party review	No

**APPLICANT**

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Company	<b>Trace America, Inc.</b>
Location	Miami, FL, US
Contact	RAY LOPEZ
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/k880794/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026