

**K151978 EDAN i15 Blood Gas and Chemistry Analysis System,  
EDAN i15 Calibrant Fluid Pack, EDAN i15 Blood Gas and  
Electrolyte Control, EDAN i15 Hematocrit Control**Jul 15, 2016  
364 days to decisionK151978 · Product code: **CHL** · Chemistry  
Source: <https://www.510kdatabase.net/k151978/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Jul 17, 2015
Decision date	Jul 15, 2016
Days to decision	364 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edan Instruments, Inc.</b>
Location	Shenzhen, CN
Contact	TRACY YUE
Website	<a href="https://www.edan.com.cn">https://www.edan.com.cn</a>
510(k) history	92 submissions · 92 cleared · 2004-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151978/> 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 2, 2026