

**K873577 GEM-STAT, GEM-PAK 2, GEM-CHECK, GEM-CRIT CHECK**Apr 28, 1988  
238 days to decisionK873577 · Product code: **CHL** · Chemistry  
Source: <https://www.510kdatabase.net/k873577/>**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	Sep 3, 1987
Decision date	Apr 28, 1988
Days to decision	238 days
Third-party review	No

**APPLICANT**

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Company	<b>Diamond Sensor Systems</b>
Location	Ann Arbor, MI, US
Contact	ENZER, PH.D.
510(k) history	3 submissions · 3 cleared · 1987-1988

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k873577/>. 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 29, 2026