

**K880829 GDS ENZYMATIC ACETAMINOPHEN REAGENT**May 27, 1988  
87 days to decisionK880829 · Product code: **LDP** · Toxicology  
Source: <https://www.510kdatabase.net/k880829/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetry, Acetaminophen (LDP)
Date received	Mar 1, 1988
Decision date	May 27, 1988
Days to decision	87 days
Third-party review	No

**APPLICANT**

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Company	<b>Gds Technology, LLC</b>
Location	Elkhart, IN, US
Contact	DE CASTRO
510(k) history	7 submissions · 7 cleared · 1988-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k880829/>; 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 28, 2026