

**K883327 CLINISTAT BUN (BLOOD UREA NITROGEN) REAGENT TEST**Jan 23, 1989  
168 days to decisionK883327 · Product code: **JGZ** · Chemistry  
Source: <https://www.510kdatabase.net/k883327/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	O-phthalaldehyde, Urea Nitrogen (JGZ)
Date received	Aug 8, 1988
Decision date	Jan 23, 1989
Days to decision	168 days
Third-party review	No

**APPLICANT**

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Company	<b>Heraeus Kulzer, Inc.</b>
Location	Elkhart, IN, US
Contact	ROSANNE M SAVOL
510(k) history	145 submissions · 145 cleared · 1988-2009

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883327/>; 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 May 20, 2026