

**K852044 CULTURETTE BRAND RAPID LATEX TEST  
CLOSTRIDIUM TOXI**Jul 19, 1985  
71 days to decisionK852044 · Product code: LLH · Microbiology  
Source: <https://www.510kdatabase.net/k852044/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	May 9, 1985
Decision date	Jul 19, 1985
Days to decision	71 days
Third-party review	No

**APPLICANT**

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Company	<b>Marion Laboratories, Inc.</b>
Location	Mchenry, IL, US
Contact	WILLIAM H GUINTY
510(k) history	38 submissions · 34 cleared · 1978-1989

Marion Laboratories, Inc. was a U.S. pharmaceutical company based in Kansas City, Missouri, specializing in bringing to market drugs discovered but unmarketed by other companies. The company operated from 1950 until 1996. Marion Laboratories received FDA 510(k) clearances from total submissions between 1978 and 1989. The company's cleared devices span General & Plastic Surgery, Toxicology, and Microbiology categories, reflecting a diverse regulatory portfolio during its active period. This company is now a historical record. No FDA 510(k) clearances have been issued since...

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