

**K863485 MODIFICATION OF CDT(TM) CLOSTRIDIUM TEST**Sep 17, 1986  
8 days to decisionK863485 · Product code: LLH · Microbiology  
Source: <https://www.510kdatabase.net/k863485/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Sep 9, 1986
Decision date	Sep 17, 1986
Days to decision	8 days
Third-party review	No

**APPLICANT**

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Company	<b>Marion Laboratories, Inc.</b>
Location	Mchenry, IL, US
Contact	GUINTY, JR
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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