

**K990664 PRIMA SYSTEM - OLD, BARTELS ELISA - NEW**Mar 31, 1999  
30 days to decisionK990664 · Product code: **LLH** · Microbiology  
Source: <https://www.510kdatabase.net/k990664/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Mar 1, 1999
Decision date	Mar 31, 1999
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intracel Corp.</b>
Location	Cambridge, MA, US
Contact	CECILIA MATOS-ROSA
510(k) history	5 submissions · 5 cleared · 1995-2000

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