

K980185 COLORPAC TOXIN AJul 17, 1998
178 days to decisionK980185 · Product code: **LLH** · Microbiology
Source: <https://www.510kdatabase.net/k980185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Jan 20, 1998
Decision date	Jul 17, 1998
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bd Becton Dickinson Vacutainer Systems Preanalytic
Location	Washington, DC, US
Contact	COLLEEN A ROHRBECK
510(k) history	632 submissions · 625 cleared · 1976-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980185/> Data sourced from FDA 510(k) public records (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. - Generated May 21, 2026