

K992196 BIOLOGIC-DT SYSTEM (BIOLOGIC-DT-1000 WITH DT-1000-TK)Sep 10, 1999
72 days to decisionK992196 · Product code: **FLD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k992196/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Hemoperfusion, Sorbent (FLD)
Date received	Jun 30, 1999
Decision date	Sep 10, 1999
Days to decision	72 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hemocleanse, Inc.
Location	West Lafayette, IN, US
Contact	STEPHEN R ASH
510(k) history	5 submissions · 5 cleared · 1994-1999

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