

**K984546 BIOLOGIC-DT MACHINE, MODEL DT-1000 AND
BIOLOGIC-DT TREATMENT KIT, MODEL DT-1000-TK**

Aug 13, 1999
234 days to decision

K984546 · Product code: FLD · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k984546/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Hemoperfusion, Sorbent (FLD)
Date received	Dec 22, 1998
Decision date	Aug 13, 1999
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

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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Device record: <https://www.510kdatabase.net/k984546/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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