

**K973457 CHROMALEX E. COLI 0157 LATEX TEST SYSTEM,
 PROD. NO. 800**

Jan 2, 1998
 112 days to decision

K973457 · Product code: **GMZ** · Microbiology
 Source: <https://www.510kdatabase.net/k973457/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Types, Escherichia Coli (GMZ)
Date received	Sep 12, 1997
Decision date	Jan 2, 1998
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shared Systems, Inc.
Location	Martinez, GA, US
Contact	ROBERT C HICKS
510(k) history	5 submissions · 5 cleared · 1992-1998

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k973457/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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