

K002011 GLUTARTEST 1 REAGENT STRIPJan 22, 2001
203 days to decisionK002011 · Product code: **MSY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k002011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Strip, Test, Reagent, Residuals For Dialysate, Disinfectant (MSY)
Date received	Jul 3, 2000
Decision date	Jan 22, 2001
Days to decision	203 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Integrated Biomedical Technology, Inc.
Location	Elkhart, IN, US
Contact	WEN H WU
510(k) history	3 submissions · 3 cleared · 1996-2001

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