

K823850 BAC-T-SCREEN BACTERIURIA DETECTION DEVMar 1, 1983
70 days to decisionK823850 · Product code: **JXA** · Microbiology
Source: <https://www.510kdatabase.net/k823850/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Screening, Urine (JXA)
Date received	Dec 21, 1982
Decision date	Mar 1, 1983
Days to decision	70 days
Third-party review	No

APPLICANT

Company	Marion Laboratories, Inc.
Location	Mchenry, IL, US
510(k) history	38 submissions · 34 cleared · 1978-1989

Marion Laboratories, Inc. was a U.S. pharmaceutical company based in Kansas City, Missouri, specializing in bringing to market drugs discovered but unmarketed by other companies. The company operated from 1950 until 1996. Marion Laboratories received FDA 510(k) clearances from total submissions between 1978 and 1989. The company's cleared devices span General & Plastic Surgery, Toxicology, and Microbiology categories, reflecting a diverse regulatory portfolio during its active period. This company is now a historical record. No FDA 510(k) clearances have been issued since...

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