

K833917 BAC-T-SCREENJan 13, 1984
60 days to decisionK833917 · Product code: **JTA** · Chemistry
Source: <https://www.510kdatabase.net/k833917/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Microbial Growth (JTA) |
| Date received | Nov 14, 1983 |
| Decision date | Jan 13, 1984 |
| Days to decision | 60 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...
