

**K853073 CULTURETTE BRAND 10-MINUTE GROUP A STREP
I.D.**Aug 1, 1985
9 days to decisionK853073 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k853073/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antisera, All Groups, Streptococcus Spp. (GTZ) |
| Date received | Jul 23, 1985 |
| Decision date | Aug 1, 1985 |
| Days to decision | 9 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Marion Laboratories, Inc. |
| Location | Mchenry, IL, US |
| Contact | WILLIAM H GUINTY |
| 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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