FDA 510(k) Premarket Notification

K821100 MERITECASTREP (TM)

CLEARED

May 13, 1982
23 days to decision

K821100 · Product code: **GTZ** · Microbiology
Source: https://www.510kdatabase.net/k821100/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Apr 20, 1982
Decision date	May 13, 1982
Days to decision	23 days
Third-party review	No

APPLICANT

Company	**Meridian Diagnostics, Inc.**
Location	Walker, MI, US
510(k) history	92 submissions · 92 cleared · 1980-1999

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k821100/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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