FDA 510(k) Premarket Notification

K880665 MODIFIED GROUP A STREPTOCOCCUS DETECTION KIT

CLEARED

Mar 1, 1988
12 days to decision

K880665 · Product code: **GTZ** · Microbiology
Source: https://www.510kdatabase.net/k880665/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Feb 18, 1988
Decision date	Mar 1, 1988
Days to decision	12 days
Third-party review	No

APPLICANT

Company	**Allelix Diagnostics, Inc.**
Location	Canada L4v 1p1, CA
Contact	JANET SHAW
510(k) history	2 submissions · 2 cleared · 1988-1989