FDA 510(k) Premarket Notification

K912868 GROUP A STREP POSITIVE AND NEGATIVE CONTROLS

CLEARED

Aug 7, 1991
40 days to decision

K912868 · Product code: **GTZ** · Microbiology
Source: https://www.510kdatabase.net/k912868/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Jun 28, 1991
Decision date	Aug 7, 1991
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Quidel Corp.**
Location	Washington, DC, US
Contact	CRAIG E WATSON
510(k) history	93 submissions · 93 cleared · 1983-2013