FDA 510(k) Premarket Notification

CLEARED

K120169 INTERLAB IFE TEST USING G 26 VER. 2.0 INSTRUMENT

Aug 24, 2012
218 days to decision

K120169 · Product code: **CFF** · Immunology
Source: https://www.510kdatabase.net/k120169/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoelectrophoretic, Immunoglobulins, (g, A, M) (CFF)
Date received	Jan 19, 2012
Decision date	Aug 24, 2012
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Grifols USA, LLC**
Location	Los Angeles, CA, US
Contact	Gary Lehnus
510(k) history	2 submissions · 2 cleared · 2012-2012