FDA 510(k) Premarket Notification

K812222 EM-X

CLEARED

Sep 23, 1981
47 days to decision

K812222 · Product code: **KSG** · Immunology
Source: https://www.510kdatabase.net/k812222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Potentiating For In Vitro Diagnostic Use (KSG)
Date received	Aug 7, 1981
Decision date	Sep 23, 1981
Days to decision	47 days
Third-party review	No

APPLICANT

Company	**Biological Corp. of America**
Location	Mchenry, IL, US
510(k) history	6 submissions · 6 cleared · 1976-1982