FDA 510(k) Premarket Notification

K802930 CYTOMEGALO VIRUS & CONTROLS

CLEARED

Jan 9, 1981
51 days to decision

K802930 · Product code: **GQH** · Microbiology
Source: https://www.510kdatabase.net/k802930/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Cytomegalovirus (GQH)
Date received	Nov 19, 1980
Decision date	Jan 9, 1981
Days to decision	51 days
Third-party review	No

APPLICANT

Company	**Orion Diagnostica, Inc.**
Location	Mchenry, IL, US
510(k) history	28 submissions · 28 cleared · 1980-1994