FDA 510(k) Premarket Notification

K881932 ORTHO* CYTOMEGALOVIRUS IDENTIFICATION REAGENT

CLEARED

Aug 1, 1988
83 days to decision

K881932 · Product code: **GQH** · Microbiology
Source: https://www.510kdatabase.net/k881932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Cytomegalovirus (GQH)
Date received	May 10, 1988
Decision date	Aug 1, 1988
Days to decision	83 days
Third-party review	No

APPLICANT

Company	**Ortho Diagnostic Systems, Inc.**
Location	Carpinteria, CA, US
Contact	LARRY D MCCLAIN,PHD
510(k) history	126 submissions · 126 cleared · 1981-1997