

K854488 ORTHO HSV ANTIGEN ELISA TESTFeb 4, 1986
88 days to decisionK854488 · Product code: **GQN** · Microbiology
Source: <https://www.510kdatabase.net/k854488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Herpesvirus Hominis 1,2 (GQN)
Date received	Nov 8, 1985
Decision date	Feb 4, 1986
Days to decision	88 days
Third-party review	No

APPLICANT

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

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