

K880604 COLORGENE HSV DNA HYBRIDIZATION TESTAug 3, 1988
173 days to decisionK880604 · Product code: **GQN** · Microbiology
Source: <https://www.510kdatabase.net/k880604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Herpesvirus Hominis 1,2 (GQN)
Date received	Feb 12, 1988
Decision date	Aug 3, 1988
Days to decision	173 days
Third-party review	No

APPLICANT

Company	Enzo Biochem, Inc.
Location	New York, NY, US
Contact	J OLSIEWSKI
510(k) history	5 submissions · 5 cleared · 1987-1988

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