

K842830 IMMUNOPER-OXIDASE TEST KIT FOR DETECT OFNov 26, 1985
494 days to decisionK842830 · Product code: **GQN** · Microbiology
Source: <https://www.510kdatabase.net/k842830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Herpesvirus Hominis 1,2 (GQN)
Date received	Jul 20, 1984
Decision date	Nov 26, 1985
Days to decision	494 days
Third-party review	No

APPLICANT

Company	Bartels Immunodiagnostic Supplies, Inc.
Location	Mchenry, IL, US
510(k) history	35 submissions · 34 cleared · 1981-1986

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Device record: <https://www.510kdatabase.net/k842830/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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