

K822026 IMMUNO DIAGNOSTICS ASSAYAug 3, 1982
22 days to decisionK822026 · Product code: **CZP** · Chemistry
Source: <https://www.510kdatabase.net/k822026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Iga, Antigen, Antiserum, Control (CZP)
Date received	Jul 12, 1982
Decision date	Aug 3, 1982
Days to decision	22 days
Third-party review	No

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013

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Device record: <https://www.510kdatabase.net/k822026/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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