

**K891683 TITAN GEL IFE FREE KAPPA/LAMBA LIGHT CHAIN
ANTISER**Apr 12, 1989
21 days to decisionK891683 · Product code: **CZN** · Immunology
Source: <https://www.510kdatabase.net/k891683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Iga, Fitc, Antigen, Antiserum, Control (CZN)
Date received	Mar 22, 1989
Decision date	Apr 12, 1989
Days to decision	21 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k891683/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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