

K802283 ANTISERA TO HUMAN FREE KAPPA CHAINSOct 23, 1980
34 days to decisionK802283 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k802283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Sep 19, 1980
Decision date	Oct 23, 1980
Days to decision	34 days
Third-party review	No

APPLICANT

Company	Kallestad Laboratories, Inc.
Location	Mchenry, IL, US
510(k) history	92 submissions · 92 cleared · 1976-1986

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k802283/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026