

K810863 KALLESTAD HEP-2 CELL LINE SUBSTRATEApr 14, 1981
14 days to decisionK810863 · Product code: **DBM** · Immunology
Source: <https://www.510kdatabase.net/k810863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	Mar 31, 1981
Decision date	Apr 14, 1981
Days to decision	14 days
Third-party review	No

APPLICANT

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

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