

K831941 LEAP RHEUMATOID FACTOR TEST KITJul 18, 1983
32 days to decisionK831941 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k831941/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Jun 16, 1983
Decision date	Jul 18, 1983
Days to decision	32 days
Third-party review	No

APPLICANT

Company	Cooper Diagnostics, Inc.
Location	Mchenry, IL, US
510(k) history	1 submissions · 1 cleared · 1983-1983

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k831941/> 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 July 1, 2026