

K831036 ENA TEST KIT SM & RNP AUTO ANTIBODYApr 27, 1983
27 days to decisionK831036 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k831036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Mar 31, 1983
Decision date	Apr 27, 1983
Days to decision	27 days
Third-party review	No

APPLICANT

Company	Calbiochem-Behring Corp.
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1978-1983

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k831036/> 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