

**K000489 ENZYME IMMUNOASSAY ANTI-CENTROMERE
ANTIBODY TEST**Apr 5, 2000
51 days to decisionK000489 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k000489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Feb 14, 2000
Decision date	Apr 5, 2000
Days to decision	51 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Helix Diagnostics, Inc.
Location	West Sacramento, CA, US
Contact	VIRGINIA CAPPEL
510(k) history	15 submissions · 15 cleared · 1991-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000489/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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