

K200199 ADVIA Centaur CA 125IIApr 6, 2020
70 days to decisionK200199 · Product code: LTK · Immunology
Source: <https://www.510kdatabase.net/k200199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Jan 27, 2020
Decision date	Apr 6, 2020
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Fatima Pacheco
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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