

K192777 ADVIA Centaur CA 15-3 assayNov 22, 2019
53 days to decisionK192777 · Product code: **MOI** · Immunology
Source: <https://www.510kdatabase.net/k192777/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Sep 30, 2019
Decision date	Nov 22, 2019
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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