

K193397 ADVIA Centaur® Digoxin assayJul 16, 2021
588 days to decisionK193397 · Product code: **KXT** · Toxicology
Source: <https://www.510kdatabase.net/k193397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Dec 6, 2019
Decision date	Jul 16, 2021
Days to decision	588 days
Third-party review	No
Combination product	No
PCCP authorized	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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