

K191296 Pointe Scientific Creatinine Kinase (CK) Reagent SetAug 11, 2020
455 days to decisionK191296 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k191296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	May 14, 2019
Decision date	Aug 11, 2020
Days to decision	455 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtest DX
Location	Lincoln Park, MI, US
Contact	William Cripps
510(k) history	2 submissions · 2 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191296/> 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 15, 2026