FDA 510(k) Premarket Notification

CLEARED

K251281 Nova Max Creat eGFR Monitoring System

Jan 21, 2026
272 days to decision

K251281 · Product code: **SHB** · Chemistry
Source: https://www.510kdatabase.net/k251281/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Creatinine Test System For At Home Prescription Use (SHB)
Date received	Apr 24, 2025
Decision date	Jan 21, 2026
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nova Biomedical Corporation**
Location	Waltham, MA, US
Contact	Mariya Cesnulevicius
510(k) history	40 submissions · 40 cleared · 2011-2026