

K221813 Nova Allegro UACR Assay, Nova Allegro AnalyzerNov 19, 2024
881 days to decisionK221813 · Product code: **CGX** · Chemistry
Source: <https://www.510kdatabase.net/k221813/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Dual Track |
| Device classification | Alkaline Picrate, Colorimetry, Creatinine (CGX) |
| Date received | Jun 22, 2022 |
| Decision date | Nov 19, 2024 |
| Days to decision | 881 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nova Biomedical Corporation |
| Location | Waltham, MA, US |
| Contact | Cesidio Tempesta |
| 510(k) history | 40 submissions · 40 cleared · 2011-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221813/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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