

K200204 Stat Profile Prime Plus Analyzer SystemApr 6, 2020
69 days to decisionK200204 · Product code: **GGZ** · Chemistry
Source: <https://www.510kdatabase.net/k200204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxyhemoglobin (GGZ)
Date received	Jan 28, 2020
Decision date	Apr 6, 2020
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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