

K180186 Stat Profile Prime Plus Analyzer SystemAug 23, 2018
212 days to decisionK180186 · Product code: **GGZ** · Chemistry
Source: <https://www.510kdatabase.net/k180186/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxyhemoglobin (GGZ)
Date received	Jan 23, 2018
Decision date	Aug 23, 2018
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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