

K203790 GEM Premier 5000Aug 20, 2021
235 days to decisionK203790 · Product code: **CHL** · Chemistry
Source: <https://www.510kdatabase.net/k203790/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Dec 28, 2020
Decision date	Aug 20, 2021
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Instrumentation Laboratory CO
Location	Mchenry, IL, US
Contact	Gabriella Erdosy
510(k) history	321 submissions · 320 cleared · 1976-2023

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