

K061974 GEM PREMIER 4000 WITH IQM, MODEL 4000Sep 15, 2006
65 days to decisionK061974 · Product code: **CHL** · Chemistry
Source: <https://www.510kdatabase.net/k061974/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Jul 12, 2006
Decision date	Sep 15, 2006
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary
Other names	GEM CVP 1 AND 2 WITH CO-OX; GEM CVP 3 AND 4 HEMATOCRIT

APPLICANT

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

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