

K160412 GEM Premier 5000 (Measured Parameters: pH, pCO2 and pO2)

Dec 14, 2016
306 days to decision

K160412 · Product code: **CHL** · Chemistry
Source: <https://www.510kdatabase.net/k160412/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Feb 12, 2016
Decision date	Dec 14, 2016
Days to decision	306 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160412/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026