

K131126 OPTI CCA-TS2Aug 22, 2013
122 days to decisionK131126 · Product code: **CHL** · Chemistry
Source: <https://www.510kdatabase.net/k131126/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL) |
| Date received | Apr 22, 2013 |
| Decision date | Aug 22, 2013 |
| Days to decision | 122 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Opti Medical Systems, Inc. |
| Location | Roswell, GA, US |
| Contact | LEN OWENS |
| 510(k) history | 3 submissions · 3 cleared · 2011-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131126/> 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 May 26, 2026