

K192340 OptoMonitorDec 12, 2019
106 days to decisionK192340 · Product code: **DXO** · Cardiovascular
Source: <https://www.510kdatabase.net/k192340/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transducer, Pressure, Catheter Tip (DXO) |
| Date received | Aug 28, 2019 |
| Decision date | Dec 12, 2019 |
| Days to decision | 106 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Opsens, Inc. |
| Location | Quebec, CA |
| Contact | Marc Chaunet |
| 510(k) history | 10 submissions · 10 cleared · 2015-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192340/> 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 25, 2026