

K191420 Reusable SpO2 SensorOct 11, 2019
136 days to decisionK191420 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k191420/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter (DQA) |
| Date received | May 28, 2019 |
| Decision date | Oct 11, 2019 |
| Days to decision | 136 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shenzhen Changke Connect Electronics Co., Ltd. |
| Location | Longgang District, Shenzhen, CN |
| Contact | Yahui Zhou |
| 510(k) history | 8 submissions · 8 cleared · 2019-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191420/> 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 27, 2026