

K201294 Pulse OximeterNov 27, 2020
197 days to decisionK201294 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k201294/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter (DQA) |
| Date received | May 14, 2020 |
| Decision date | Nov 27, 2020 |
| Days to decision | 197 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Guangdong Long Yao Electronic Technology Co., Ltd. |
| Location | Guangzhou, CN |
| Contact | Lei Wang |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Chonconn Medical Device Consulting Co., Ltd. |
| Contact | Kevin Wang |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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