FDA 510(k) Premarket Notification

# K201294 Pulse Oximeter

**CLEARED**

Nov 27, 2020
197 days to decision

K201294 · 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