FDA 510(k) Premarket Notification

# K190869 Pulse Oximeter

**CLEARED**

Sep 13, 2019
163 days to decision

K190869 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k190869/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter (DQA) |
| Date received | Apr 3, 2019 |
| Decision date | Sep 13, 2019 |
| Days to decision | 163 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Shenzhen Aeon Technology Co., Ltd.** |
| Location | Shenzhen, CN |
| Contact | Xie Hua |
| 510(k) history | 3 submissions · 3 cleared · 2017-2020 |

## REGULATORY CONSULTANT

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|---|---|
| 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