FDA 510(k) Premarket Notification

# K191088 Checkme O2 Pulse Oximeter

**CLEARED**

Dec 2, 2019
222 days to decision

K191088 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k191088/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter (DQA) |
| Date received | Apr 24, 2019 |
| Decision date | Dec 2, 2019 |
| Days to decision | 222 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Shenzhen Viatom Technology Co., Ltd.** |
| Location | Shen Zhen, CN |
| Contact | Zhou Saixin |
| 510(k) history | 5 submissions · 5 cleared · 2019-2025 |