

**K243049 Pulse Oximeter (FS20P)**Jan 2, 2025  
97 days to decisionK243049 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k243049/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 27, 2024
Decision date	Jan 2, 2025
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Pulse Oximeter (FS20C); Pulse Oximeter (FS10C)

**APPLICANT**

---

Company	<b>Hunan Accurate Bio-Medical Technology Co., Ltd.</b>
Location	Changsha, Hunan, CN
Contact	Li Zhang
510(k) history	5 submissions · 5 cleared · 2014-2026

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Chonconn Medical Device Consulting Co., Ltd.</b>
Contact	Jie Yang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243049/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026