

K192608 Disposable SpO2 SensorJan 24, 2020
126 days to decisionK192608 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k192608/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 20, 2019
Decision date	Jan 24, 2020
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Sino-K Medical Technology Co.,Ltd
Location	Baoan District, Shenzhen, CN
Contact	Lao Chengxin
510(k) history	3 submissions · 3 cleared · 2020-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192608/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026