

K223740 Oxygen Concentrator (Model: KSW-5, KSN-5, KSOC-5)Oct 5, 2023
295 days to decisionK223740 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k223740/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Generator, Oxygen, Portable (CAW) |
| Date received | Dec 14, 2022 |
| Decision date | Oct 5, 2023 |
| Days to decision | 295 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Jiangsu Konsung Bio-Medical Science and Technology Co., Ltd. |
| Location | Jiangsu, CN |
| Contact | Heidi Zhang |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

REGULATORY CONSULTANT

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|-----------------|---|
| Consulting firm | Share Info (Guangzhou) Medical Consultant , Ltd. |
| Contact | Cassie Lee |

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.netDevice record: <https://www.510kdatabase.net/k223740/> 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 25, 2026