

K230379 Portable (Ultrasonic) NebulizerNov 27, 2023
287 days to decisionK230379 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k230379/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nebulizer (direct Patient Interface) (CAF) |
| Date received | Feb 13, 2023 |
| Decision date | Nov 27, 2023 |
| Days to decision | 287 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dongguan Simzo Electronic Technology Co., Ltd. |
| Location | Dongguan, CN |
| Contact | Jack Jin |
| 510(k) history | 3 submissions · 3 cleared · 2018-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Shenzhen Reanny Medical Devices Management Consulting., Ltd. |
| Contact | Reanny Wang |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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