

K180837 CONTEC Oxygen ConcentratorJan 10, 2019
286 days to decisionK180837 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k180837/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Mar 30, 2018
Decision date	Jan 10, 2019
Days to decision	286 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Contec Medical System Co., Ltd.
Location	Zhong Shan, Shanghai, CN
Contact	Xueyong Li
510(k) history	12 submissions · 12 cleared · 2008-2019

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180837/> 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 June 18, 2026