

K243956 TG-980P CO2 Sensor Kit (TG-980P)Jun 10, 2025
169 days to decisionK243956 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k243956/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Dec 23, 2024
Decision date	Jun 10, 2025
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	TG-980P1 CO2 Sensor Kit (TG-980P1)

APPLICANT

Company	Nihon Kohden Corporation
Location	Tokyo, JP
Contact	Sandra Gadeyne
510(k) history	18 submissions · 18 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	Nihon Kohden America, LLC
Contact	Charlemagne Chua

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

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