

K173770 OJR215 Pressure Relief ManifoldApr 5, 2019
480 days to decisionK173770 · Product code: **CBP** · Anesthesiology
Source: <https://www.510kdatabase.net/k173770/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valve, Non-rebreathing (CBP)
Date received	Dec 11, 2017
Decision date	Apr 5, 2019
Days to decision	480 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fisher & Paykel Healthcare Limited
Location	Auckland, NZ
Contact	Adele Bindon
510(k) history	8 submissions · 8 cleared · 2012-2025

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