

**K882438 CONSTANT CURRENT PERIPHERAL NERVE STIM.
#NS252**Jul 18, 1988
34 days to decisionK882438 · Product code: **BXN** · Anesthesiology
Source: <https://www.510kdatabase.net/k882438/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Battery-powered (BXN) |
| Date received | Jun 14, 1988 |
| Decision date | Jul 18, 1988 |
| Days to decision | 34 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Fisher &Paykel Healthcare , Ltd. |
| Location | Auckland, New Zealand, NZ |
| Contact | DAVID MILBURN |
| Website | https://www.fphcare.com/ |
| 510(k) history | 70 submissions · 70 cleared · 1988-2025 |

Fisher &Paykel Healthcare, Ltd. is a medical device manufacturer based in Auckland, New Zealand. The company has driven innovation in healthcare technologies for over 50 years. Fisher &Paykel Healthcare has received FDA 510(k) clearances from total submissions since 1988. The company specializes in Anesthesiology devices, which represent 91% of its regulatory submissions. The latest clearance was granted in 2025, confirming active ongoing development. Recent cleared devices include high-flow nasal therapy systems, noninvasive ventilation masks, and respiratory support int...
