FDA 510(k) Premarket Notification

**CLEARED**

# K003704 OPTOVENT RESPONS, OPTOVENT RENEE (OPTOVENT RESPONS WITHOUT PULSE OXIMETRY MODULE)

Feb 5, 2001
66 days to decision

K003704 · Product code: **BZQ** · Anesthesiology
Source: https://www.510kdatabase.net/k003704/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Breathing Frequency (BZQ) |
| Date received | Dec 1, 2000 |
| Decision date | Feb 5, 2001 |
| Days to decision | 66 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Optovent AB** |
| Location | Fort Lee, NJ, US |
| Contact | CLAES RYMOND |
| 510(k) history | 1 submissions · 1 cleared · 2001-2001 |