

K243562 CuffGuardAug 12, 2025
267 days to decisionK243562 · Product code: **BSK** · AnesthesiologySource: <https://www.510kdatabase.net/k243562/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cuff, Tracheal Tube, Inflatable (BSK) |
| Date received | Nov 18, 2024 |
| Decision date | Aug 12, 2025 |
| Days to decision | 267 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Idmed |
| Location | Marseille, FR |
| Contact | Aurelie Gruener |
| 510(k) history | 3 submissions · 3 cleared · 2018-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243562/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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