

K101532 NESSI OTC SPACERSep 1, 2010
90 days to decisionK101532 · Product code: **NVO** · Anesthesiology
Source: <https://www.510kdatabase.net/k101532/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Spacer, Direct Patient Interface (NVO) |
| Date received | Jun 3, 2010 |
| Decision date | Sep 1, 2010 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Pharmacaribe |
| Location | Bonita Springs, FL, US |
| Contact | PAUL DRYDEN |
| 510(k) history | 4 submissions · 4 cleared · 2009-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101532/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026