

**K191858 Pylant Monitor**Feb 24, 2020  
228 days to decisionK191858 · Product code: **BSK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k191858/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Cuff, Tracheal Tube, Inflatable (BSK) |
| Date received         | Jul 11, 2019                          |
| Decision date         | Feb 24, 2020                          |
| Days to decision      | 228 days                              |
| Third-party review    | No                                    |
| Combination product   | No                                    |
| PCCP authorized       | No                                    |
| Summary / Statement   | Summary                               |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Kal-Med, LLC</b>                   |
| Location       | Kensington, CT, US                    |
| Contact        | Sandra Greenwood                      |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191858/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 18, 2026