

K233445 Bactiseal CathetersJan 17, 2024
90 days to decisionK233445 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k233445/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Shunt, Central Nervous System And Components (JXG) |
| Date received | Oct 19, 2023 |
| Decision date | Jan 17, 2024 |
| Days to decision | 90 days |
| Third-party review | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Bactiseal Barium Striped Catheters; Bactiseal Endoscopic Ventricular Catheter |

APPLICANT

| | |
|----------------|--|
| Company | Integra Lifesciences Production Corporation |
| Location | Mansfield, MA, US |
| Contact | Amanda Erwin |
| 510(k) history | 8 submissions · 8 cleared · 2021-2025 |

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