

**K162620 Remel Spectra ESBL**May 1, 2017  
223 days to decisionK162620 · Product code: **JSO** · Microbiology  
Source: <https://www.510kdatabase.net/k162620/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Culture Media, Antimicrobial Susceptibility Test, Excluding Mueller Hinton Agar (JSO) |
| Date received         | Sep 20, 2016  |
| Decision date         | May 1, 2017   |
| Days to decision      | 223 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Remel, Inc.</b>                      |
| Location       | Lenexa, KS, US                          |
| Contact        | CYNTHIA KNAPP                           |
| 510(k) history | 17 submissions · 17 cleared · 1994-2017 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162620/> 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 1, 2026