

**K994343 BACT/ALERT SV**Feb 10, 2000  
49 days to decisionK994343 · Product code: **MDB** · Microbiology  
Source: <https://www.510kdatabase.net/k994343/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, Blood Culturing (MDB)      |
| Date received         | Dec 23, 1999                       |
| Decision date         | Feb 10, 2000                       |
| Days to decision      | 49 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Organon Teknika Corp.</b>              |
| Location       | Mchenry, IL, US                           |
| Contact        | REBECCA A RIVAS                           |
| 510(k) history | 130 submissions · 129 cleared · 1980-2000 |

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