

K030067 VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG CONTROLSJan 17, 2003
10 days to decisionK030067 · Product code: **MJX** · Microbiology
Source: <https://www.510kdatabase.net/k030067/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Kit, Serological, Positive Control (MJX) |
| Date received | Jan 7, 2003 |
| Decision date | Jan 17, 2003 |
| Days to decision | 10 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ortho-Clinical Diagnostics |
| Location | Rochester, NY, US |
| Contact | SARAH PARSONS |
| 510(k) history | 38 submissions · 38 cleared · 1999-2024 |

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunochemistry. Now part of QuidelOrtho, the brand operates with global research and development centered in Rochester, New York. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Recent clearances span chemistry devices, immunology assays, and microbiology reagents, reflecting the company's focus on diagnostic platforms and assays for disease detection and blood compatibility testing. The V...

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Device record: <https://www.510kdatabase.net/k030067/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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