

K931862 NINHYDRIN REAGENTJun 15, 1993
62 days to decisionK931862 · Product code: **JTO** · Microbiology
Source: <https://www.510kdatabase.net/k931862/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Discs, Strips And Reagents, Microorganism Differentiation (JTO) |
| Date received | Apr 14, 1993 |
| Decision date | Jun 15, 1993 |
| Days to decision | 62 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|-------------------------------------------|
| Company | Hardy Diagnostics |
| Location | Santa Maria, CA, US |
| Contact | MELISSA M TRAYLOR |
| 510(k) history | 109 submissions · 109 cleared · 1993-2026 |

Hardy Diagnostics is an American health care company headquartered in Santa Maria, California. The company manufactures bacteriological culture media, reagents, automated microscope slide staining machines, and rapid identification kits for microbiological testing. Hardy Diagnostics has received FDA 510(k) clearances from total submissions since 1993. The company specializes exclusively in Microbiology devices, with its most recent clearance in 2025. Recent cleared devices include antibiotic susceptibility testing disks and viral transport media. The company manufactures ...

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