FDA 510(k) Premarket Notification

# K810510 YA-CRYPTO ANTIBODY TUBE AGGLUTINATION

**CLEARED**

Mar 20, 1981
24 days to decision

K810510 · Product code: **GMD** · Microbiology
Source: https://www.510kdatabase.net/k810510/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antisera, Latex Agglutination, Cryptococcus Neoformans (GMD) |
| Date received | Feb 24, 1981 |
| Decision date | Mar 20, 1981 |
| Days to decision | 24 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Immuno-Mycologics, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 26 submissions · 26 cleared · 1979-2012 |