

K123368 LATEX POWDER FREE EXAMINATION GLOVES WITH COLLOIDAL OATMEAL USP SKIN PROTECTANTMay 7, 2013
187 days to decisionK123368 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k123368/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Nov 1, 2012 |
| Decision date | May 7, 2013 |
| Days to decision | 187 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Hartalega Sdn Bhd |
| Location | Kuala Lumpur, MY |
| Contact | NURUL AISYAH KONG |
| 510(k) history | 61 submissions · 61 cleared · 1989-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123368/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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