

**K061078 BRIGHT ELEMENT SND BHD LATEX POWDER FREE
EXAMINATION GLOVES**May 19, 2006
32 days to decisionK061078 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k061078/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Apr 17, 2006 |
| Decision date | May 19, 2006 |
| Days to decision | 32 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bright Element Sdn Bhd |
| Location | Klang Selangor Darul Ehsan, MY |
| Contact | SEOW L AUDIE |
| 510(k) history | 4 submissions · 4 cleared · 2006-2007 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061078/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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