FDA 510(k) Premarket Notification

# K980204 DUREX LATEX CONDOMS

**CLEARED**

Apr 17, 1998
87 days to decision

K980204 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k980204/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Condom (HIS) |
| Date received | Jan 20, 1998 |
| Decision date | Apr 17, 1998 |
| Days to decision | 87 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **London Intl., LLC** |
| Location | Dothan, AL, US |
| Contact | NEIL ANDERSON |
| 510(k) history | 6 submissions · 6 cleared · 1998-1998 |