

K113056 ORANGE COLORED CONDOMS ORANGE SCENTJul 3, 2012
263 days to decisionK113056 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k113056/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Condom (HIS) |
| Date received | Oct 14, 2011 |
| Decision date | Jul 3, 2012 |
| Days to decision | 263 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Karex Industries Sdn. Bhd. |
| Location | Pontian Kecil, Jalan Johor, MY |
| Contact | LAI PENG LIM |
| 510(k) history | 8 submissions · 8 cleared · 2007-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113056/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026