

K865106 PROPHYLACTIC (CONDOM) MR. JOHNNYMay 20, 1987
140 days to decisionK865106 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k865106/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Condom (HIS) |
| Date received | Dec 31, 1986 |
| Decision date | May 20, 1987 |
| Days to decision | 140 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Medelec Intl. Corp. |
| Location | Miami Beach, FL, US |
| Contact | DOCAL, M.D. |
| 510(k) history | 15 submissions · 15 cleared · 1985-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k865106/>; 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 June 30, 2026