

K965064 ROSTAM APPLICATOR TAMPON/ROSTAM NON APPLICATOR TAMPONFeb 20, 1997
64 days to decisionK965064 · Product code: **HEB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k965064/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tampon, Menstrual, Unscented (HEB) |
| Date received | Dec 18, 1996 |
| Decision date | Feb 20, 1997 |
| Days to decision | 64 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Rostam , Ltd. |
| Location | Allendale, NJ, US |
| Contact | DONNA GALERMAN |
| 510(k) history | 9 submissions · 9 cleared · 1997-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k965064/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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