

K983586 HTF MEDIUM, MODIFIED HTF MEDIUM- HEPES, HTF POWDER (WITHOUT ANTIBIOTICS), MODIFIED HTG POWDER- HEPES (WITHOUT ANTIBODITI

Feb 18, 1999
128 days to decision

K983586 · Product code: **MQL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k983586/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Media, Reproductive (MQL) |
| Date received | Oct 13, 1998 |
| Decision date | Feb 18, 1999 |
| Days to decision | 128 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Irvine Scientific Sales Co., Inc. |
| Location | Santa Ana, CA, US |
| Contact | ROBERTA L JOHNSON |
| 510(k) history | 40 submissions · 40 cleared · 1997-2017 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k983586/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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