

K844173 FEMTESTAug 14, 1985
293 days to decisionK844173 · Product code: **HES** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k844173/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Insufflator, Carbon-dioxide, Uterotubal (and Accessories) (HES) |
| Date received | Oct 25, 1984 |
| Decision date | Aug 14, 1985 |
| Days to decision | 293 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bionexus, Inc. |
| Location | Raleigh, NC, US |
| Contact | CHARLES R DESMET |
| 510(k) history | 2 submissions · 2 cleared · 1985-1987 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k844173/>; 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