

K910518 GLOVE-N-GEL AMNIOTOMY KITMay 9, 1991
92 days to decisionK910518 · Product code: **HGE** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k910518/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------|
| Decision | Substantially Equivalent - K |
| Submission type | Traditional |
| Device classification | Amniotome (HGE) |
| Date received | Feb 6, 1991 |
| Decision date | May 9, 1991 |
| Days to decision | 92 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Epcom Medical Systems, Inc. |
| Location | Walker, MI, US |
| Contact | PAUL ULBRICH |
| 510(k) history | 13 submissions · 12 cleared · 1981-1991 |

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