

K905654 ELECTROSURGICAL UNIT WITH ACCESSORIESMar 18, 1991
90 days to decisionK905654 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k905654/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Dec 18, 1990 |
| Decision date | Mar 18, 1991 |
| Days to decision | 90 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Aspen Labs |
| Location | Utica, NY, US |
| Contact | JANE JOHNSON |
| 510(k) history | 6 submissions · 6 cleared · 1991-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k905654/>; 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 29, 2026