

K920819 ABDOVAC (TM), BELLOVAC (TM) AND EXUDRAINMar 24, 1993
394 days to decisionK920819 · Product code: **GCY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k920819/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent - K |
| Submission type | Traditional |
| Device classification | Apparatus, Suction, Single Patient Use, Portable, Nonpowered (GCY) |
| Date received | Feb 24, 1992 |
| Decision date | Mar 24, 1993 |
| Days to decision | 394 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Astra Meditec AB |
| Location | Sweden, SE |
| Contact | GOSTA WENNERSTORM |
| 510(k) history | 3 submissions · 2 cleared · 1988-1993 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k920819/> 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 July 2, 2026