

K780818 LAPAROTOMY SPONGEJun 22, 1978
36 days to decisionK780818 · Product code: **EFQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k780818/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gauze/sponge, Internal (EFQ) |
| Date received | May 17, 1978 |
| Decision date | Jun 22, 1978 |
| Days to decision | 36 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Qualtex, Inc. |
| Location | Walker, MI, US |
| 510(k) history | 2 submissions · 2 cleared · 1978-1990 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k780818/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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