FDA 510(k) Premarket Notification

# K832040 STERILE FLUID PRODUCING UNIT #EP550

**CLEARED**

Sep 29, 1983
97 days to decision

K832040 · Product code: **LJH** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k832040/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Irrigation, Urological (LJH) |
| Date received | Jun 24, 1983 |
| Decision date | Sep 29, 1983 |
| Days to decision | 97 days |
| Third-party review | No |

## APPLICANT

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|---|---|
| Company | **American Cystocope Makers, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 9 submissions · 9 cleared · 1976-1983 |