FDA 510(k) Premarket Notification

# K896941 AMS DYNAFLEX SELF CONTAINED PENILE PROSTHESIS

**CLEARED**

Mar 6, 1990
83 days to decision

K896941 · Product code: **FAE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k896941/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Penile (FAE) |
| Date received | Dec 13, 1989 |
| Decision date | Mar 6, 1990 |
| Days to decision | 83 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **American Medical Systems, Inc.** |
| Location | Mchenry, IL, US |
| Contact | DENNIS TOUSSAINT |
| 510(k) history | 72 submissions · 72 cleared · 1979-2013 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k896941/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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