

K974637 ELECTRODES/PROBES/DEVICESJan 7, 1998
26 days to decisionK974637 · Product code: **FAS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k974637/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Electrosurgical, Active, Urological (FAS) |
| Date received | Dec 12, 1997 |
| Decision date | Jan 7, 1998 |
| Days to decision | 26 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ximed/Prosure/Injectx |
| Location | San Jose, CA, US |
| Contact | ASHVIN DESAI |
| 510(k) history | 9 submissions · 9 cleared · 1995-2001 |

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