FDA 510(k) Premarket Notification

# K964777 TZ

**CLEARED**

Jan 3, 1997
37 days to decision

K964777 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k964777/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Biopsy (KNW) |
| Date received | Nov 27, 1996 |
| Decision date | Jan 3, 1997 |
| Days to decision | 37 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Gallini Intl., Inc.** |
| Location | Cliffside Park, NJ, US |
| Contact | PAUL L HAWTHORNE |
| 510(k) history | 7 submissions · 7 cleared · 1996-1997 |