FDA 510(k) Premarket Notification

# K994336 BITX PROBES

**CLEARED**

Feb 8, 2000
47 days to decision

K994336 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k994336/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Dec 23, 1999 |
| Decision date | Feb 8, 2000 |
| Days to decision | 47 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Everest Medical Corp.** |
| Location | Brooklyn Center, MN, US |
| Contact | FREDERICK G MADES |
| 510(k) history | 21 submissions · 21 cleared · 1987-2000 |