FDA 510(k) Premarket Notification

# K953271 ELMED RF-ALERT

**CLEARED**

Jan 18, 1996
189 days to decision

K953271 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k953271/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Jul 13, 1995 |
| Decision date | Jan 18, 1996 |
| Days to decision | 189 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Elmed, Inc.** |
| Location | Mchenry, IL, US |
| Contact | WERNER HAUSNER |
| 510(k) history | 26 submissions · 26 cleared · 1977-2001 |