FDA 510(k) Premarket Notification

# K902416 SURELITE AND SURELITE XL BLOOD LANCET

**CLEARED**

Aug 1, 1990
62 days to decision

K902416 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k902416/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK) |
| Date received | May 31, 1990 |
| Decision date | Aug 1, 1990 |
| Days to decision | 62 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Gainor Medical Europe, Ltd.** |
| Location | Mcdonough, GA, US |
| Contact | MARK GAINOR |
| 510(k) history | 13 submissions · 13 cleared · 1990-1994 |