FDA 510(k) Premarket Notification

# K943521 VIOTEC 1400 SERIES ULTRAVIOLET GERMICIDAL FIXTURE

**CLEARED**

Feb 14, 1995
209 days to decision

K943521 · Product code: **FRA** · General Hospital
Source: https://www.510kdatabase.net/k943521/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Purifier, Air, Ultraviolet, Medical (FRA) |
| Date received | Jul 20, 1994 |
| Decision date | Feb 14, 1995 |
| Days to decision | 209 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Schiff & Co.** |
| Location | West Cadwell, NJ, US |
| Contact | ROBERT SCHIFF |
| 510(k) history | 15 submissions · 15 cleared · 1988-1999 |