

K103409 ALLERGEAZE R CLEARMar 15, 2011
113 days to decisionK103409 · Product code: **KXF** · General Hospital
Source: <https://www.510kdatabase.net/k103409/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Applicator, Absorbent Tipped, Non-sterile (KXF) |
| Date received | Nov 22, 2010 |
| Decision date | Mar 15, 2011 |
| Days to decision | 113 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Smartpractice |
| Location | Phoenix, AZ, US |
| Contact | KIM SULLIVAN |
| 510(k) history | 4 submissions · 4 cleared · 2002-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103409/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026