

**K012221 SAFE AT HOME CHOLESTEROL PROFILE BLOOD
COLLECTION AND TRANSPORT SYSTEM**Apr 3, 2002
261 days to decisionK012221 · Product code: **JKA** · Chemistry
Source: <https://www.510kdatabase.net/k012221/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA) |
| Date received | Jul 16, 2001 |
| Decision date | Apr 3, 2002 |
| Days to decision | 261 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biosafe Laboratories, Inc. |
| Location | Lake Forest, IL, US |
| Contact | JACK A MAGGIORE |
| 510(k) history | 6 submissions · 6 cleared · 1999-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012221/> 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 28, 2026