

K041522 FLEXI-STAT DISPOSABLE ADHESIVE SPO2 SENSORSSep 14, 2004
99 days to decisionK041522 · Product code: **DQA** · AnesthesiologySource: <https://www.510kdatabase.net/k041522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jun 7, 2004
Decision date	Sep 14, 2004
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Elekon Industries U.S.A., Inc.
Location	Plano, TX, US
Contact	KRISTA OAKES
510(k) history	6 submissions · 6 cleared · 2004-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041522/> 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 May 25, 2026