

K042675 FLEXI-STAT SP02 EAR SENSORDec 6, 2004
68 days to decisionK042675 · Product code: **DPZ** · Anesthesiology
Source: <https://www.510kdatabase.net/k042675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Ear (DPZ)
Date received	Sep 29, 2004
Decision date	Dec 6, 2004
Days to decision	68 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/k042675/> 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