

K032291 TOSCA PCO2, SPO2 AND PULSE RATE MONITORING SYSTEMAug 24, 2004
397 days to decisionK032291 · Product code: **DOA** · Toxicology
Source: <https://www.510kdatabase.net/k032291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Digoxin (125-i), Goat Antibody, Anion Exchange, Resin Sep. (DOA)
Date received	Jul 24, 2003
Decision date	Aug 24, 2004
Days to decision	397 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Linde Medical Sensors AG
Location	Basel, CH
Contact	JEAN-PIERRE PALMA
510(k) history	4 submissions · 4 cleared · 1999-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032291/>, 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