FDA 510(k) Premarket Notification

K003004 OSCAR 2, MODEL 222

CLEARED

Oct 25, 2000
30 days to decision

K003004 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k003004/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 25, 2000
Decision date	Oct 25, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Suntech Medical Instruments, Inc.**
Location	Raleigh, NC, US
Contact	GEORGE MYERS
510(k) history	5 submissions · 5 cleared · 1992-2001

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k003004/ 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