

**K003609 N-MID OSTEOCALCIN ONE STEP ELISA MODEL
30SC4000**May 16, 2001
175 days to decisionK003609 · Product code: **NEO** · Chemistry
Source: <https://www.510kdatabase.net/k003609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Osteocalcin (NEO)
Date received	Nov 22, 2000
Decision date	May 16, 2001
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteometer Biotech A/S
Location	Herlev, DK
Contact	PER QVIST
510(k) history	2 submissions · 2 cleared · 1999-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003609/>; 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 30, 2026