

K031604 GLYCOMARKSep 22, 2003
123 days to decisionK031604 · Product code: **NOZ** · Chemistry
Source: <https://www.510kdatabase.net/k031604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, 1,5-anhydroglucitol (15ag) (NOZ)
Date received	May 22, 2003
Decision date	Sep 22, 2003
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tomen America, Inc.
Location	New York, NY, US
Contact	Erika B Ammirati
510(k) history	1 submissions · 1 cleared · 2003-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031604/> 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 29, 2026