

K122925 NEW STETIC ARTIFICIAL TEETHFeb 12, 2013
141 days to decisionK122925 · Product code: **ELM** · Dental
Source: <https://www.510kdatabase.net/k122925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Denture, Plastic, Teeth (ELM)
Date received	Sep 24, 2012
Decision date	Feb 12, 2013
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	New Stetic
Location	Apollo Beach, FL, US
Contact	JOHN OBRIEN
510(k) history	3 submissions · 3 cleared · 2011-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122925/> 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 7, 2026