

**K011450 SILICONE IMPRESSION MATERIAL**Jun 13, 2001  
33 days to decisionK011450 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k011450/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	May 11, 2001
Decision date	Jun 13, 2001
Days to decision	33 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Northeast Resins &amp; Silicones, LLC</b>
Location	Cheshire, CT, US
Contact	SIVANANDA S JADA
510(k) history	1 submissions · 1 cleared · 2001-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011450/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 2, 2026