

**K080246 COMPOSITE ALIGNER BUTTON**Apr 11, 2008  
71 days to decisionK080246 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k080246/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jan 31, 2008
Decision date	Apr 11, 2008
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Dentsply Interntional</b>
Location	York, PA, US
Contact	HELEN LEWIS
510(k) history	13 submissions · 13 cleared · 2007-2009

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080246/> 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 June 22, 2026