

**K994357 BITEM LOCK, MODELS SW006, SW012**Mar 14, 2000  
78 days to decisionK994357 · Product code: **EJF** · DentalSource: <https://www.510kdatabase.net/k994357/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Metal, Orthodontic (EJF)
Date received	Dec 27, 1999
Decision date	Mar 14, 2000
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Thermoelastic Technologies, Inc.</b>
Location	Appollo Beach, FL, US
Contact	ART WARD
510(k) history	2 submissions · 2 cleared · 2000-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k994357/> 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