

**K113401 ORTHO-1(NOT FINALIZED)**Feb 7, 2012  
82 days to decisionK113401 · Product code: **DYH** · Dental  
Source: <https://www.510kdatabase.net/k113401/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Nov 17, 2011
Decision date	Feb 7, 2012
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bisco, Inc.</b>
Location	Mchenry, IL, US
Contact	Michelle Schiltz-Taing
510(k) history	88 submissions · 88 cleared · 1984-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113401/> 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 15, 2026