

**K150359 Tensyn Plug**May 7, 2015  
84 days to decisionK150359 · Product code: **HTN** · Orthopedic  
Source: <https://www.510kdatabase.net/k150359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Washer, Bolt Nut (HTN)
Date received	Feb 12, 2015
Decision date	May 7, 2015
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dallen Medical, Inc.</b>
Location	San Clemente, CA, US
Contact	Al Memmolo
510(k) history	10 submissions · 10 cleared · 2013-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150359/> 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 May 16, 2026