

**K143092 Tensyn Plug**Feb 11, 2015  
106 days to decisionK143092 · Product code: **HTN** · Orthopedic  
Source: <https://www.510kdatabase.net/k143092/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Washer, Bolt Nut (HTN)
Date received	Oct 28, 2014
Decision date	Feb 11, 2015
Days to decision	106 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/k143092/> 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