

K133858 TENSYN BANDFeb 28, 2014
71 days to decisionK133858 · Product code: **HTN** · Orthopedic
Source: <https://www.510kdatabase.net/k133858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Washer, Bolt Nut (HTN)
Date received	Dec 19, 2013
Decision date	Feb 28, 2014
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dallen Medical, Inc.
Location	San Clemente, CA, US
Contact	AL MEMMOLO
510(k) history	10 submissions · 10 cleared · 2013-2017

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