

K150125 Elite Nitinol Fixation SystemMay 11, 2015
111 days to decisionK150125 · Product code: **JDR** · Orthopedic
Source: <https://www.510kdatabase.net/k150125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Jan 20, 2015
Decision date	May 11, 2015
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomedical Enterprises, Inc.
Location	San Antonio, TX, US
Contact	Joe Soward
510(k) history	10 submissions · 10 cleared · 2002-2016

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