

K151876 Bio2 Fusion Implant SystemDec 30, 2015
174 days to decisionK151876 · Product code: **HTY** · Orthopedic
Source: <https://www.510kdatabase.net/k151876/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Jul 9, 2015
Decision date	Dec 30, 2015
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio2 Technologies, Inc.
Location	Woburn, MA, US
Contact	Janet Krevolin
510(k) history	3 submissions · 3 cleared · 2014-2016

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