

**K163488 Flex-Thread Clavicle Pin System**Mar 20, 2017  
98 days to decisionK163488 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k163488/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Dec 12, 2016
Decision date	Mar 20, 2017
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Intrafuse, LLC</b>
Location	Logan, UT, US
Contact	Robert Hoy
510(k) history	2 submissions · 2 cleared · 2017-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163488/> 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