

K153638 Bicortical Fixation Screw & Washer Nut SystemApr 19, 2016
123 days to decisionK153638 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k153638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Dec 18, 2015
Decision date	Apr 19, 2016
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	First Ray, LLC
Location	Logan, UT, US
Contact	ROBERT HOY
510(k) history	4 submissions · 4 cleared · 2016-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153638/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026