

K162805 Akros Fibulink Syndesmosis Repair KitJan 10, 2017
97 days to decisionK162805 · Product code: **HTN** · Orthopedic
Source: <https://www.510kdatabase.net/k162805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Washer, Bolt Nut (HTN)
Date received	Oct 5, 2016
Decision date	Jan 10, 2017
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Akros Medical
Location	Durham, NC, US
Contact	Charles Horrell
510(k) history	3 submissions · 3 cleared · 2017-2020

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