

K173550 Akros FibuLink™ Syndesmosis Repair KitDec 14, 2017
28 days to decisionK173550 · Product code: **HTN** · Orthopedic
Source: <https://www.510kdatabase.net/k173550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Washer, Bolt Nut (HTN)
Date received	Nov 16, 2017
Decision date	Dec 14, 2017
Days to decision	28 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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