

K152527 Integra DigiFuse Cannulated Intramedullary Fusion System

Oct 29, 2015
56 days to decision

K152527 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k152527/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 3, 2015
Decision date	Oct 29, 2015
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ascension Orthopedics
Location	Austin, TX, US
Contact	Jayana Kenana
510(k) history	7 submissions · 7 cleared · 2014-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k152527/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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