

**K162153 Integra® CAPTURE™ Screw System & Integra® Ti6®
Internal Fixation System**Jul 14, 2017
346 days to decisionK162153 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k162153/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 2, 2016
Decision date	Jul 14, 2017
Days to decision	346 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162153/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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