

K161616 DePuy Synthes 4.0 mm and 4.5 mm Cortex Screws, DePuy Synthes 2.4 mm Cannulated Screws, DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws, DePuy Synthes 4.5 mm Cannulated Screws, DePuy Synthes 6.5 mm Cannulated Screws, DePuy Synthes 7.0 mm and 7.3 mm Cannulated Screws, DePuy Synthes 1.5 mm Headless Compression Screws, DePuy Synthes 2.4 mm Headless Compression Screws, DePuy Synthes 3.0 mm Headless Compression Screws, DePuy Synthes 4.5 mm and 6.5 mm Headless Compression Screw

Feb 16, 2017
248 days to decision

K161616 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k161616/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 13, 2016
Decision date	Feb 16, 2017
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes USA Products, LLC
Location	West Chester, PA, US
Contact	Nina Rudolph
510(k) history	60 submissions · 60 cleared · 2010-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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