

K160553 DePuy Synthes 4.0 mm and 5.0 mm Locking Screws – MR Conditional, DePuy Synthes Wrist Fusion Plate (WFP) – MR Conditional, DePuy Synthes Large Fragment Dynamic Compression Locking (DCL) System –MR Conditional, DePuy Synthes Small Fragment Dynamic Compression Locking (DCL) System – MR Conditional, DePuy Synthes Modular Foot System – MR Conditional, DePuy Synthes T-Plates – MR Conditional, DePuy Synthes One-third Tubular Plate with Collar (OTPC) – MR Conditional, DePuy Synthes Stainless S

Jun 30, 2017
487 days to decision

K160553 · Product code: HRS · Orthopedic
Source: <https://www.510kdatabase.net/k160553/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 29, 2016
Decision date	Jun 30, 2017
Days to decision	487 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes (Usa) Products, LLC / Depuy Orthopaedics, Inc.
Location	19380, PA, US
Contact	ELIZABETH JACOBS
510(k) history	5 submissions · 5 cleared · 2017-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160553/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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