

K201346 DePuy Synthes Retrograde Femoral Nail Advanced System, DePuy Synthes Locking Screws for Medullary Nails, 5.0 mm

Sep 23, 2020
125 days to decision

K201346 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k201346/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	May 21, 2020
Decision date	Sep 23, 2020
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k201346/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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