FDA 510(k) Premarket Notification

K963192 SYNTHES STERILE 3.5 MM AND 4.0 MM CANNULATED SCREWS

CLEARED

Nov 8, 1996
85 days to decision

K963192 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k963192/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 15, 1996
Decision date	Nov 8, 1996
Days to decision	85 days
Third-party review	No

APPLICANT

Company	**Synthes (Usa)**
Location	Mchenry, IL, US
Contact	ANGELA J SILVESTRI
510(k) history	411 submissions · 394 cleared · 1977-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k963192/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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