FDA 510(k) Premarket Notification

K970097 PROXIMAL FEMORAL NAIL (PFN) SYSTEM

CLEARED

Mar 13, 1997
59 days to decision

K970097 · Product code: **JDW** · Orthopedic
Source: https://www.510kdatabase.net/k970097/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Threaded (JDW)
Date received	Jan 13, 1997
Decision date	Mar 13, 1997
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Synthes (Usa)**
Location	Mchenry, IL, US
Contact	SHERI L MUSGNUNG
510(k) history	411 submissions · 394 cleared · 1977-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k970097/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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