FDA 510(k) Premarket Notification

K963045 SYNTHES (U.S.A.) UNIVERSAL SACRAL SYSTEM

CLEARED

Feb 13, 1997
192 days to decision

K963045 · Product code: **MNH** · Orthopedic
Source: https://www.510kdatabase.net/k963045/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Aug 5, 1996
Decision date	Feb 13, 1997
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Synthes (Usa)**
Location	Mchenry, IL, US
Contact	DIANE T BROWN
510(k) history	411 submissions · 394 cleared · 1977-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k963045/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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