FDA 510(k) Premarket Notification

K970912 LEIBINGER SELF-DRILLING SCREW

CLEARED

Oct 1, 1997
203 days to decision

K970912 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k970912/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Mar 12, 1997
Decision date	Oct 1, 1997
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Howmedica Leibinger, Inc.**
Location	Dallas, TX, US
Contact	KRISTYN WASKI
510(k) history	11 submissions · 10 cleared · 1996-1997