FDA 510(k) Premarket Notification

K033303 WAFER SYSTEM

CLEARED

Jun 24, 2004
254 days to decision

K033303 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k033303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Oct 14, 2003
Decision date	Jun 24, 2004
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spine Wave, Inc.**
Location	Shelton, CT, US
Contact	RONALD K SMITH
510(k) history	57 submissions · 57 cleared · 2004-2025