FDA 510(k) Premarket Notification

K964362 KINAMED PROFIX SYSTEM

CLEARED

Jan 16, 1997
76 days to decision

K964362 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k964362/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Nov 1, 1996
Decision date	Jan 16, 1997
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Kinamed, Inc.**
Location	Los Angeles, CA, US
Contact	ROBERT BRUCE
510(k) history	33 submissions · 29 cleared · 1988-2013