

**K010322 ISKD (INTRAMEDULLARY SKELETAL KINETIC
DISTRACTOR)**May 2, 2001
89 days to decisionK010322 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k010322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Feb 2, 2001
Decision date	May 2, 2001
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthodyne, Inc.
Location	Orlando, FL, US
Contact	CARL KNOBLOCH
510(k) history	1 submissions · 1 cleared · 2001-2001

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