

K092381 IBALANCE AKRFX MEDIAL OPENING WEDGE TIBIAL SYSTEM, IFX MEDIAL PEEK IMPLANT AND ANCHOR, AKRFX INSTRUMENTATIONOct 27, 2009
83 days to decisionK092381 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k092381/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 5, 2009
Decision date	Oct 27, 2009
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ibalance Medical, Inc.
Location	Philadelphia, PA, US
Contact	JANICE M HOGAN
510(k) history	1 submissions · 1 cleared · 2009-2009

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