

K032167 BIO-INTRAFIX TIBIAL SCREW AND SHEATHOct 15, 2003
91 days to decisionK032167 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k032167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jul 16, 2003
Decision date	Oct 15, 2003
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mitek Worldwide
Location	Norwood, MA, US
Contact	KAREN K SYLVIA
510(k) history	10 submissions · 10 cleared · 2002-2004

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