K081244 LOWER EXTREMITY EXTERNAL FIXATION - EXPANDED INDICATIONS

CLEARED

Jul 30, 2008
90 days to decision

K081244 · Product code: **KTT** · Orthopedic
Source: https://www.510kdatabase.net/k081244/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	May 1, 2008
Decision date	Jul 30, 2008
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Trauma**
Location	Parsippany, NJ, US
Contact	PATRICIA S BERES
510(k) history	7 submissions · 7 cleared · 2007-2009

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k081244/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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