

**K081392 BIORETEC ACTIVASCREW, ACTIVASCREW
CANNULATED AND ACTIVASCREW CANNULATED WITH
ACTIVAPIN**Jun 18, 2008
30 days to decisionK081392 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k081392/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	May 19, 2008
Decision date	Jun 18, 2008
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioretec, Ltd.
Location	Tampere, FI
Contact	MARI RUOTSALAINEN
510(k) history	9 submissions · 8 cleared · 2006-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081392/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026