

**K130716 BIORETEC ACTIVASCREW INTERFERENCE**Aug 28, 2013  
166 days to decisionK130716 · Product code: **MAI** · Orthopedic  
Source: <https://www.510kdatabase.net/k130716/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Mar 15, 2013
Decision date	Aug 28, 2013
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130716/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026