

**K080879 ACTIVATM PRODUCT GROUP INCLUDING  
BIOABSORBABLE DEVICES ACTIVAPIN FUSION,  
ACTIVANAILT™ CONICAL™**Jun 24, 2008  
85 days to decisionK080879 · Product code: HTY · Orthopedic  
Source: <https://www.510kdatabase.net/k080879/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Mar 31, 2008
Decision date	Jun 24, 2008
Days to decision	85 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/k080879/>; 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