

**K972919 BIOFIX BIOABSORBABLE SELF-REINFORCED POLY-L-LACTIDE THREADED BROWLIFT SCREW**Mar 27, 1998  
232 days to decisionK972919 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k972919/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 7, 1997
Decision date	Mar 27, 1998
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bionx Implants, Inc.</b>
Location	Tampere, FL
Contact	JONATHAN S KAHAN
510(k) history	18 submissions · 18 cleared · 1998-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972919/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 20, 2026