

**K003659 PLGA PIN, MODEL 171120,171140,171520,171540,171560,172020,172040,172060,173240,173260**Feb 20, 2001  
84 days to decisionK003659 · Product code: HTY · Orthopedic  
Source: <https://www.510kdatabase.net/k003659/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Nov 28, 2000
Decision date	Feb 20, 2001
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bionx Implants, Inc.</b>
Location	Tampere, FI
Contact	TUIJA ANNALA
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/k003659/>; 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 20, 2026