

**K010051 POLY-TAPES WITH THE FASTLOK FIXATION DEVICE**Jul 13, 2001  
186 days to decisionK010051 · Product code: **JDR** · Orthopedic  
Source: <https://www.510kdatabase.net/k010051/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Jan 8, 2001
Decision date	Jul 13, 2001
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xiros Plc</b>
Location	Leeds, GB
Contact	JIM ROWLAND
510(k) history	2 submissions · 2 cleared · 2001-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010051/> 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 21, 2026