

**K222978 Poly-Tape/Infinity-Lock Soft Tissue Reinforcement Device**Dec 27, 2022  
90 days to decisionK222978 · Product code: **QUW** · Orthopedic  
Source: <https://www.510kdatabase.net/k222978/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Mesh, Surgical, Non-resorbable, Orthopedics, Reinforcement Of Ligament (QUW) |
| Date received         | Sep 28, 2022   |
| Decision date         | Dec 27, 2022   |
| Days to decision      | 90 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Xiros, Ltd.</b>                    |
| Location       | Leeds, GB                             |
| Contact        | Steve Curran                          |
| 510(k) history | 9 submissions · 9 cleared · 2015-2023 |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222978/> 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 26, 2026