

**K170146 Galaxy UNYCO System**Oct 12, 2017  
268 days to decisionK170146 · Product code: **KTT** · Orthopedic  
Source: <https://www.510kdatabase.net/k170146/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT) |
| Date received         | Jan 17, 2017  |
| Decision date         | Oct 12, 2017  |
| Days to decision      | 268 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Orthofix Srl</b>                     |
| Location       | Rockville, MD, US                       |
| Contact        | Gianluca Ricadona                       |
| 510(k) history | 36 submissions · 36 cleared · 1995-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170146/> 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 16, 2026