

**K223795 FairFix QT Adjustable Button**Jan 17, 2023  
29 days to decisionK223795 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k223795/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Special  |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received         | Dec 19, 2022   |
| Decision date         | Jan 17, 2023   |
| Days to decision      | 29 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Medacta International S.A.</b>                             |
| Location       | Castel San Pietro, CH   |
| Contact        | Stefano Baj   |
| Website        | <a href="https://www.medacta.com">https://www.medacta.com</a> |
| 510(k) history | 164 submissions · 164 cleared · 2008-2026                     |

**REGULATORY CONSULTANT**

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|-----------------|--------------------|
| Consulting firm | <b>Medacta USA</b> |
| Contact         | Chris Lussier      |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223795/> 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 14, 2026