

**K221855 Universal CMF System**Nov 9, 2022  
135 days to decisionK221855 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k221855/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Plate, Bone (JEY)                  |
| Date received         | Jun 27, 2022                       |
| Decision date         | Nov 9, 2022                        |
| Days to decision      | 135 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Stryker Leibinger GmbH &amp; Co KG</b> |
| Location       | Freiburg Im Breisgau, DE                  |
| Contact        | Amelia Kesti                              |
| 510(k) history | 21 submissions · 21 cleared · 2009-2026   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221855/> 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 14, 2026