

**K203341 ACS LD Uni FB Knee System**Jan 8, 2021  
57 days to decisionK203341 · Product code: **HSX** · Orthopedic  
Source: <https://www.510kdatabase.net/k203341/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX) |
| Date received         | Nov 12, 2020   |
| Decision date         | Jan 8, 2021  |
| Days to decision      | 57 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Implantcast GmbH</b>   |
| Location       | Buxtehude, DE   |
| Contact        | Juliane Hoepfner  |
| Website        | <a href="https://www.implantcast.com">https://www.implantcast.com</a> |
| 510(k) history | 19 submissions · 19 cleared · 2017-2026                               |

Implantcast GmbH is an innovative medical device manufacturer specializing in orthopedic implants. Based in Buxtehude, Germany, the company develops and produces primary, revision, and tumor endoprostheses for hip, knee, shoulder, and ankle applications. Since 1988, implantcast has grown to over 800 employees and serves a global distribution network across more than 64 countries. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on orthopedic devices. Clearances span from 2017 to 2026, demonstrating sustained regulatory ac...

**REGULATORY CONSULTANT**

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|-----------------|------------------|
| Consulting firm | <b>Mcra, LLC</b> |
| Contact         | Dave McGurl      |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k203341/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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