

**K200045 MUTARS Cemented Femoral Stems**Oct 16, 2020  
282 days to decisionK200045 · Product code: **MEH** · Orthopedic  
Source: <https://www.510kdatabase.net/k200045/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Jan 8, 2020
Decision date	Oct 16, 2020
Days to decision	282 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 Hoppner
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	Lindsay Kleinwaks

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/k200045/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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