

**K180263 EcoFit Vit E Acetabular System**Jul 20, 2018  
171 days to decisionK180263 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k180263/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Jan 30, 2018
Decision date	Jul 20, 2018
Days to decision	171 days
Third-party review	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...