

K231657 AGILON® XO Shoulder Replacement SystemFeb 16, 2024
254 days to decisionK231657 · Product code: **KWT** · Orthopedic
Source: <https://www.510kdatabase.net/k231657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	Jun 7, 2023
Decision date	Feb 16, 2024
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Implantcast GmbH
Location	Buxtehude, DE
Contact	Juliane Höppner
Website	https://www.implantcast.com
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

Consulting firm	Mcra, LLC
Contact	Sarah Pleaugh

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