FDA 510(k) Premarket Notification

CLEARED

K191433 AGILON® XO Shoulder Replacement System

Nov 12, 2020
533 days to decision

K191433 · Product code: **HSD** · Orthopedic
Source: https://www.510kdatabase.net/k191433/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (HSD)
Date received	May 29, 2019
Decision date	Nov 12, 2020
Days to decision	533 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Implantcast GmbH**
Location	Buxtehude, DE
Contact	Juliane Hoppner
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	**MRCA, LLC**
Contact	Dave McGurl

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