FDA 510(k) Premarket Notification

K232790 KONG®-TL VBR System and KONG® C VBR System

CLEARED

Apr 4, 2024
206 days to decision

K232790 · Product code: **MQP** · Orthopedic
Source: https://www.510kdatabase.net/k232790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Sep 11, 2023
Decision date	Apr 4, 2024
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Icotec AG**
Location	Altstaetten, SE
Contact	Marina Hess
510(k) history	16 submissions · 16 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Justin Eggleton

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