

K200235 KONG-TL VBR System, KONG-C VBR SystemMay 29, 2020
120 days to decisionK200235 · Product code: **MQP** · Orthopedic
Source: <https://www.510kdatabase.net/k200235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Jan 30, 2020
Decision date	May 29, 2020
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200235/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026