FDA 510(k) Premarket Notification

K232792 icotec Interbody Cage System (icotec Cervical Cage, icotec PLIF Lumbar Cage, icotec ETurn™ TLIF Lumbar Cage)

CLEARED

Apr 5, 2024
207 days to decision

K232792 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k232792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 11, 2023
Decision date	Apr 5, 2024
Days to decision	207 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