FDA 510(k) Premarket Notification

K170890 TELIX K Interbody System

CLEARED

Jun 2, 2017
67 days to decision

K170890 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k170890/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 27, 2017
Decision date	Jun 2, 2017
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biedermann Motech GmbH & Co. KG**
Location	Villingen-Schwenningen, DE
Contact	Gerd Federle
510(k) history	4 submissions · 4 cleared · 2016-2021