FDA 510(k) Premarket Notification

K151773 CONCORDE Bullet Lumbar Interbody System

CLEARED

Nov 20, 2015
143 days to decision

K151773 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k151773/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 30, 2015
Decision date	Nov 20, 2015
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medos International SARL**
Location	Raynham, MA, US
Contact	JACLYN PORSOLT
510(k) history	96 submissions · 96 cleared · 2010-2026