FDA 510(k) Premarket Notification

CLEARED

K170643 Interbody Fusion (IBF)/Vertebral Body Replacement (VBR) System

Apr 14, 2017
43 days to decision

K170643 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k170643/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 2, 2017
Decision date	Apr 14, 2017
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rti Surgical, Inc. Dba Rti Biologics**
Location	Alachua, FL, US
Contact	Jennifer Bonacci
510(k) history	2 submissions · 2 cleared · 2015-2017

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k170643/ 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 16, 2026