FDA 510(k) Premarket Notification

CLEARED

K082795 SINGLE USE PERPOS PLS SYSTEM, 4.5 BONE-LOK PLS IMPLANT

Dec 12, 2008
80 days to decision

K082795 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k082795/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Sep 23, 2008
Decision date	Dec 12, 2008
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Interventional Spine, Inc.**
Location	Irvine, CA, US
Contact	CAROL EMERSON
510(k) history	8 submissions · 7 cleared · 2008-2016