FDA 510(k) Premarket Notification

K083663 PACP

CLEARED

Feb 25, 2009
77 days to decision

K083663 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k083663/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Dec 10, 2008
Decision date	Feb 25, 2009
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pioneer Surgical Technology**
Location	Marquette, MI, US
Contact	JONATHAN GILBERT
510(k) history	50 submissions · 48 cleared · 1993-2011