FDA 510(k) Premarket Notification

K080790 MODIFICATION TO THEKEN ATOLL CERVICO-THORACIC SYSTEM

CLEARED

Apr 29, 2008
40 days to decision

K080790 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k080790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Mar 20, 2008
Decision date	Apr 29, 2008
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Theken Spine, LLC**
Location	Akron, OH, US
Contact	DALE DAVISON
510(k) history	23 submissions · 23 cleared · 2007-2012