FDA 510(k) Premarket Notification

K100243 QUINTEX CERVICAL PLATING SYSTEM

CLEARED

Sep 2, 2010
218 days to decision

K100243 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k100243/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jan 27, 2010
Decision date	Sep 2, 2010
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aesculap Implant Systems, LLC**
Location	Center Valley, PA, US
Contact	Lisa Boyle
510(k) history	22 submissions · 22 cleared · 2010-2022