FDA 510(k) Premarket Notification

K162638 CETRA Anterior Cervical Plate System

CLEARED

Dec 16, 2016
85 days to decision

K162638 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k162638/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Sep 22, 2016
Decision date	Dec 16, 2016
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthofix, Inc.**
Location	Mckinney, TX, US
Contact	Jacki Koch
510(k) history	57 submissions · 57 cleared · 1996-2024