FDA 510(k) Premarket Notification

K131200 ASPIRON ACP SYSTEM

CLEARED

Aug 29, 2013
122 days to decision

K131200 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k131200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Apr 29, 2013
Decision date	Aug 29, 2013
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**U&I Corporation**
Location	Uijeongbu-Si, Gyeonggi-Do, KR
Contact	GYEONG-JE KWON
510(k) history	23 submissions · 23 cleared · 2013-2022