FDA 510(k) Premarket Notification

K082187 BIOMET ANTERIOR LUMBAR PLATE

CLEARED

Nov 13, 2008
101 days to decision

K082187 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k082187/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Aug 4, 2008
Decision date	Nov 13, 2008
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ebi, L.P.**
Location	Parsippany, NJ, US
Contact	VIVIAN KELLY MS, RAC
510(k) history	95 submissions · 94 cleared · 1997-2010