FDA 510(k) Premarket Notification

K072321 BIOFLEX

CLEARED

Mar 25, 2008
218 days to decision

K072321 · Product code: **NQP** · Orthopedic
Source: https://www.510kdatabase.net/k072321/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Metal/polymer Spinal System, Fusion (NQP)
Date received	Aug 20, 2007
Decision date	Mar 25, 2008
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biospine Co., Ltd.**
Location	Washington, DC, US
Contact	JUSTIN EGGLETON
510(k) history	1 submissions · 1 cleared · 2008-2008