FDA 510(k) Premarket Notification

K132373 BIOMET ACCESS SYSTEM

CLEARED

Mar 27, 2014
240 days to decision

K132373 · Product code: **PDQ** · Neurology
Source: https://www.510kdatabase.net/k132373/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Nerve Locator (PDQ)
Date received	Jul 30, 2013
Decision date	Mar 27, 2014
Days to decision	240 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Spine (Aka Ebi, LLC)**
Location	Parsippany, NJ, US
Contact	VIVIAN KELLY, MS, RAC
510(k) history	13 submissions · 13 cleared · 2010-2014