FDA 510(k) Premarket Notification

K160569 NeuGuide

CLEARED

Jul 6, 2016
128 days to decision

K160569 · Product code: **PBQ** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k160569/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fixation, Non-absorbable Or Absorbable, For Pelvic Use (PBQ)
Date received	Feb 29, 2016
Decision date	Jul 6, 2016
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pop Medical Solutions**
Location	Tel Aviv, IL
Contact	Guy Ohad
510(k) history	1 submissions · 1 cleared · 2016-2016