FDA 510(k) Premarket Notification

K120831 ANCHORSURE

CLEARED

Oct 12, 2012
207 days to decision

K120831 · Product code: **PBQ** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k120831/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fixation, Non-absorbable Or Absorbable, For Pelvic Use (PBQ)
Date received	Mar 19, 2012
Decision date	Oct 12, 2012
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neomedic International S.L.**
Location	Minneapolis, MN, US
Contact	JEFFREY R SHIDEMAN
510(k) history	2 submissions · 2 cleared · 2011-2012