FDA 510(k) Premarket Notification

K131015 BIODESIGN ONLAY DURAL GRAFT OR BIODESIGN DURAPLASTY GRAFT

CLEARED

Oct 8, 2013
180 days to decision

K131015 · Product code: **GXQ** · Neurology
Source: https://www.510kdatabase.net/k131015/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Apr 11, 2013
Decision date	Oct 8, 2013
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cook Biotech, Inc.**
Location	West Lafayette, IN, US
Contact	MARY A FADERAN
510(k) history	31 submissions · 31 cleared · 1998-2014