

**K131015 BIODESIGN ONLAY DURAL GRAFT OR BIODESIGN DURAPLASTY GRAFT**Oct 8, 2013  
180 days to decisionK131015 · 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	<b>Cook Biotech, Inc.</b>
Location	West Lafayette, IN, US
Contact	MARY A FADERAN
510(k) history	31 submissions · 31 cleared · 1998-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131015/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 6, 2026