FDA 510(k) Premarket Notification

K183513 XenoSure Dura Biologic Patch

CLEARED

Jun 13, 2019
177 days to decision

K183513 · Product code: **GXQ** · Neurology
Source: https://www.510kdatabase.net/k183513/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Dec 18, 2018
Decision date	Jun 13, 2019
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**LeMaitre Vascular, Inc.**
Location	Burlington, MA, US
Contact	Xiang Zhang
510(k) history	32 submissions · 32 cleared · 2003-2022