FDA 510(k) Premarket Notification

K120600 DURAGEN SECURE DURAL REGNERATION MATRIX

CLEARED

Jun 15, 2012
108 days to decision

K120600 · Product code: **GXQ** · Neurology
Source: https://www.510kdatabase.net/k120600/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Feb 28, 2012
Decision date	Jun 15, 2012
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Integra Life Sciences**
Location	Las Vegas, NV, US
Contact	AAKASH JAIN
510(k) history	3 submissions · 3 cleared · 2011-2012