FDA 510(k) Premarket Notification

K121755 CUSTOM CRANIOFACIAL IMPLANT (CCI)

CLEARED

Sep 25, 2012
102 days to decision

K121755 · Product code: **GXN** · Neurology
Source: https://www.510kdatabase.net/k121755/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Jun 15, 2012
Decision date	Sep 25, 2012
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kelyniam Global, Inc.**
Location	New Britain, CT, US
Contact	NICHOLAS BREAULT
510(k) history	4 submissions · 4 cleared · 2011-2025