

K103582 KELYNIAM CUSTOM SKULL IMPLANT (CSI)Apr 14, 2011
127 days to decisionK103582 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k103582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Dec 8, 2010
Decision date	Apr 14, 2011
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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