

K062819 BIOPLATE RIGID BONE PLATING SYSTEM FOR CRANIOMAXILLOFACIAL SURGERY

Dec 4, 2006
75 days to decision

K062819 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k062819/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Sep 20, 2006
Decision date	Dec 4, 2006
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioplate, Inc.
Location	Los Angeles, CA, US
Contact	JESUS T FARINAS
510(k) history	23 submissions · 23 cleared · 2000-2008

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Device record: <https://www.510kdatabase.net/k062819/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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