FDA 510(k) Premarket Notification

K214109 PEEK Patient Specific Cranial/Craniofacial Implant(PSCI)

CLEARED

Oct 28, 2022
303 days to decision

K214109 · Product code: **GXN** · Neurology
Source: https://www.510kdatabase.net/k214109/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Dec 29, 2021
Decision date	Oct 28, 2022
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kontour(Xi?An) Medical Technology Co., Ltd.**
Location	Xi'An, CN
Contact	Rongrong Cong
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	Joyce Yang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov