FDA 510(k) Premarket Notification

K033868 SYNTHES (USA) PATIENT SPECIFIC CRANIAL/CRANIOFACIAL IMPLANTS

CLEARED

Jun 21, 2004
192 days to decision

K033868 · Product code: **GXN** · Neurology
Source: https://www.510kdatabase.net/k033868/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Dec 12, 2003
Decision date	Jun 21, 2004
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Synthes (Usa)**
Location	Mchenry, IL, US
Contact	LISA M BOYLE
510(k) history	411 submissions · 394 cleared · 1977-2015