FDA 510(k) Premarket Notification

K041350 SYNTHES (USA) CHRONOS

CLEARED

Jul 8, 2004
49 days to decision

K041350 · Product code: **GXP** · Neurology
Source: https://www.510kdatabase.net/k041350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Methyl Methacrylate For Cranioplasty (GXP)
Date received	May 20, 2004
Decision date	Jul 8, 2004
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Synthes (Usa)**
Location	Mchenry, IL, US
Contact	SHERI L MUSGNUNG
510(k) history	411 submissions · 394 cleared · 1977-2015