

K080331 SYNTHES CRANIOFACIAL PLATE AND SCREW SYSTEMApr 30, 2008
84 days to decisionK080331 · Product code: JEY · Dental
Source: <https://www.510kdatabase.net/k080331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Feb 6, 2008
Decision date	Apr 30, 2008
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes (Usa)
Location	Mchenry, IL, US
Contact	AMNON TALMOR
510(k) history	411 submissions · 394 cleared · 1977-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080331/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026