

**K953806 SYNTHES (USA) MIDFACIAL SYSTEM**Mar 8, 1996  
211 days to decision

K953806 · Product code: JEY · Dental

Source: <https://www.510kdatabase.net/k953806/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Aug 10, 1995
Decision date	Mar 8, 1996
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Synthes (Usa)</b>
Location	Mchenry, IL, US
Contact	ANGELA J SILVESTRI
510(k) history	411 submissions · 394 cleared · 1977-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953806/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026