FDA 510(k) Premarket Notification

# K953806 SYNTHES (USA) MIDFACIAL SYSTEM

**CLEARED**

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 | **Synthes (Usa)** |
| Location | Mchenry, IL, US |
| Contact | ANGELA J SILVESTRI |
| 510(k) history | 411 submissions · 394 cleared · 1977-2015 |