FDA 510(k) Premarket Notification

# K162594 Craniomaxillofacial Distraction System (CMFD)

**CLEARED**

May 8, 2017
234 days to decision

K162594 · Product code: **MQN** · Dental
Source: https://www.510kdatabase.net/k162594/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | External Mandibular Fixator And/or Distractor (MQN) |
| Date received | Sep 16, 2016 |
| Decision date | May 8, 2017 |
| Days to decision | 234 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Synthes USA Products, LLC** |
| Location | West Chester, PA, US |
| Contact | NICHOLAS FOUNTOULAKIS |
| 510(k) history | 60 submissions · 60 cleared · 2010-2022 |